It Takes Two to Tango:

Regulating the Emerging Risks of Microorganisms

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I. INTRODUCTION

The benefits of microorganisms to agriculture have been known at least since the late 1800's.[1] As early as 1888, the Dutch scientist Martinus Beijerink discovered that microbes known as *Rhizobia* facilitated nitrogen capture in the roots of leguminous plants.[2] For many years, before the scientists could explain the phenomenon, farmers would move soil from one farm to another to take advantage of disease prevention benefits of certain soils over others.[3] Scientists only later discovered that living organisms were responsible for these "disease suppression" characteristics.[4] With the advent of modern DNA sequencing techniques, academic and commercial researchers are now beginning to understand and map the diversity of organisms living in the rhizosphere.[5] Researchers now know, for example, that a small container of soil holds more microorganisms than all of the people who have ever lived.[6]

While much may be said about the size and complexity of the microbiome, researchers are only beginning to develop novel uses for the motley collection of bacteria, fungi, and viruses they have discovered. In the early to mid 2000's, Eric Brown, director of microbiology at the U.S. Food and Drug Administration's ("FDA") Center for Food Safety and Applied Nutrition, began to study *Salmonella* outbreaks that he eventually tracked down to infected tomato plants.[7] His working hypothesis was that *Salmonella* bacteria made its way to the plants from animal feces that mixed with the surface water used to water the plants.[8] After a couple of these incidents, Brown began to wonder why it was that these outbreaks only occurred with East Coast tomato crops.[9] If his hypothesis was correct, one would expect similar outbreaks in West Coast tomato crops as well. After careful study, Brown and his fellow researchers found communities of *Salmonella*-inhibiting bacteria called *Paenibacillus alvei* in the soil of West Coast tomato plants.[10] The absence of these bacteria in the soil of East Coast tomatoes would help explain how tomatoes on the West Coast

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1 Marla Broadfoot, *Microbes Added to Seeds Could Boost Crop Production*, SCI. AM. (Jan. 6, 2016), https://www.scientificamerican.com/article/microbes-added-to-seeds-could-boost-crop-production.

2 *Id.*

3 ANN REID & SHANNON C. REID, HOW MICROBES CAN FEED THE WORLD: A REPORT FROM THE AMERICAN ACADEMY OF MICROBIOLOGY 4 (2012).

4 *Id.*

5 Broadfoot, *supra* note 1.

6 *Id.*

7 Richard Conniff, *Microbes Help Grow Better Crops*, SCI. AM. (Sept. 1, 2013), https://www.scientificamerican.com/article/microbes-help-grow-better-crops.

8 *Id.*

9 *Id.*

10 *Id.*; *see also Nonpathogenic Bacteria, Paenibacillus alvei, Useful as a Natural Biocontrol Agent for Elimination of Food-borne Pathogenic Bacteria*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ScienceResearch/CollaborativeOpportunities/Inventions/ucm464726.htm (last updated Aug. 6, 2015) [hereinafter *Collaborative Opportunities*].

largely avoided problems with the food borne illness. Subsequently, the FDA began a pilot study in Virginia by spraying tomato plants with this bacterium and studying its effect on eliminating *Salmonella*.[11] As of 2015, the FDA was seeking industry partners to help with further research and commercialization of the bacteria as a biocontrol agent.[12]

Other agricultural uses include efforts by molecular biologist Gabriel Iturriaga in Mexico to study the effects of *Rhizobium etli* on plants.[13] The bacterium produces the sugar trehalose, which has been known to help plants resist drought by strengthening plant cell membranes, thereby making the plants more resilient to drying and rehydration cycles.[14] For years, plants such as corn and potatoes have been genetically engineered to produce the sugar, but Iturriaga hopes that his microorganism research will open up an opportunity for drought-resistant agriculture without the need to resort to genetic modification.[15]

Microbiological products have found a substantial market in the agricultural industry. In early 2016, the market for agricultural biologicals was estimated to be $2.9 billion per year.[16] Companies like Monsanto and Novozymes are investing heavily in research and development in this area,[17] in part because the regulatory framework governing their use is less cumbersome than for other agricultural products.[18] While it is hard to predict the future, the two companies are hopeful that by 2025, products they develop will be used on as much as 500 million acres, fifty percent of existing farmland in the United States.[19]

Outside of agriculture, researchers are beginning to look at using microorganisms as an alternative to the use of chemical insecticides. Earlier this year, a subsidiary of Alphabet, Google's holding company, released twenty million, bacteria-infected *Aedes aegypti* mosquitoes in Fresno in a project called "Debug Fresno."[20] The *Aedes aegypti* mosquito has been present in Fresno since at least 2013, and it is known to be a potential carrier of diseases such as Zika, dengue, and chikungunya.[21] The project functions by infecting male mosquitoes with the bacterium *Wolbachia*, which leads to low hatch rates of mosquito

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11 Conniff, *supra* note 7.

12 *Collaborative Opportunities*, *supra* note 10.

13 Conniff, *supra* note 7.

14 *Id.*

15 *Id.*

16 Broadfoot, *supra* note 1.

17 Peter Audrey Smith, *Untapped Plant Microbiome Could Help Feed Billions*, SCI. AM. (July 15, 2015), https://www.scientificamerican.com/article/untapped-plant-microbiome-could-help-feed-billions.

18 Broadfoot, *supra* note 1.

19 *Id.*

20 James Doubek, *To Shrink Mosquito Population, Scientists Are Releasing 20 Million Mosquitos*, NAT'L PUB. RADIO: THE TWO-WAY (July 21, 2017, 5:25 AM), http://www.npr.org/sections/thetwo-way/2017/07/21/538470321/to-shrink-the-mosquito-population-scientists-are-releasing-20-million-of-them.

21 *Id.*

larvae.[22] In this way, the initiative operates similarly to other attempts at controlling the mosquito population without using insecticides.[23] The bacterium has another benefit as well. Female mosquitos often transmit viruses such as Zika in their saliva when they bite,[24] but *Wolbachia* has been shown to inhibit transmission of the Zika virus in mosquito saliva.[25]

Finally, in perhaps one of the most intriguing uses of microorganisms, companies like Universal BioMining, based in Emeryville, California, are studying the use of microorganisms to aid with copper extraction.[26] Traditional copper mining techniques involve allowing a highly acidic solution to seep through piles of rock.[27] The solution extracts copper from the rock, which is then separated from the solution through electroplating.[28] This mechanism is highly energy and chemical intensive, and it leaves much of the copper behind.[29] Universal BioMining has discovered a novel use of microorganisms that increases the solubility of copper, allowing more efficient extraction.[30] Moreover, in perhaps a sign of changes to come, the company plans to genetically modify the bacteria to enhance their copper extraction characteristics and to achieve greater efficiencies than would be possible with naturally occurring bacterial samples.[31]

While the future of the microorganism industry is undoubtedly bright, as with any new technology, there are inherent risks. The dispersal of twenty million infected mosquitos, for example, is at once exciting for the prospect of eliminating debilitating viruses such as Zika, a virus known to cause severe brain damage and other birth defects in newborns.[32] At the same time, however, field tests on the scale of the one in Fresno have never been carried out before.[33] The inherent risks of releasing these mosquitos into the wild are not fully understood. The complexity of ecological systems, and our lack of knowledge of many ecological processes, for example, could lead to any number of unforeseen

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22 *Id.*

23 *See, e.g.*, Albert C. Lin, *Mismatched Regulation: Genetically Modified Mosquitoes*, 51 U.C. DAVIS L. REV. 205, 207 (2017) (discussing genetic modification of male mosquitos to produce offspring that will die before they reach maturity).

24 Doubek, *supra* note 20; *see also id.* at 208.

25 Doubek, *supra* note 20.

26 KELLY DRINKWATER ET AL., CREATING A RESEARCH AGENDA FOR THE ECOLOGICAL IMPLICATIONS OF SYNTHETIC BIOLOGY 11-12 (2014).

27 LYNN L. BERGESON ET AL., THE DNA OF THE U.S. REGULATORY SYSTEM: ARE WE GETTING IT RIGHT FOR SYNTHETIC BIOLOGY 35 (2015).

28 *Id.* at 35-36.

29 *Id.*

30 *Id.* at 36.

31 *Id.*

32 *Overview*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/zika/about/overview.html (last updated Aug. 28, 2017).

33 Doubek, *supra* note 20 (noting that this Fresno experiment is 25 times larger than previous experiments).

consequences, including significant ecosystem disruption.[34] In addition, while scientists say the *Wolbachia* bacterium used in the mosquito field tests is "not known" to infect humans,[35] this hardly sounds like the kind of definitive statement that should give the community of Fresno sweet dreams at night.

There are concerns pertaining to spraying or coating agricultural products with bacteria as well. Since many of these products eventually end up as food, there is obvious potential risk to human health.[36] Beyond that, the practice of spraying plants or coating seeds with bacteria may lead to contamination of other crops.[37] These practices could carry substantial risk if effects on other crops are not well understood. Finally, scientists have only begun to understand how bacteria interact with each other.[38] Researchers cite this as a challenge for science to overcome as it may inhibit more rapid adoption of microorganism technology.[39] However, the same lack of knowledge also establishes the inherent risk in the use of microorganisms in any open environment. The interaction of various organisms in the rhizosphere (or in the human stomach biome) could lead to equal parts benefit and disaster.

How should we regulate this risk? In many ways, the challenges faced in regulating microorganisms serve as a proxy for the challenges faced in regulating any emerging technology. With such potential for wide and beneficial use, regulators may be rightly wary of getting in the way of industry and innovation for fear of thwarting creative endeavors that could lead to tremendous benefits. Alternatively, because there is so much that is unknown about the way microorganisms will interact with the environment, the precautionary principle counsels a proactive approach to regulating this technology, especially when it may see much wider use in the coming years.

This article will focus on microorganism regulation in four parts. First, it will review the existing statutory and regulatory framework governing microbial use. Next, it will identify gaps in the existing regulatory scheme. It will then look at lessons that may be learned from existing environmental regulation from three different perspectives: the prospective command-and-control regulation of similar emerging technologies such as Genetically Modified Organisms ("GMOs"), the retrospective policies and laws that establish liability after the fact, such as may be found in tort law, and finally the law pertaining to

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34 *See Studies Document Ease of Ecosystem Disruption*, SCI. DAILY (Mar. 26, 1999), https://www.sciencedaily.com/releases/1999/03/990326062402.htm (citing two studies that show how complexity of ecosystems may lead to unpredictability as well as disruption with surprising ease).

35 Doubek, *supra* note 20.

36 Broadfoot, *supra* note 1.

37 *Id.*

38 *Id.*

39 *See id.* (noting that combinations of microbes may ultimately have a more beneficial effect than "a single blockbuster microbe" and that "[w]ith thousands of species in one gram of soil, the possible combinations are endless.")

hazardous waste which contains elements of both *ex ante* regulation and *ex post* liability. Drawing on these disparate lessons learned, the article will close with recommendations for new legislation that will allow industry to continue to innovate safely, while providing needed protection for the environment and the community.

II. EXISTING REGULATORY AND STATUTORY FRAMEWORK GOVERNING MICROORGANISMS

The Coordinated Framework for Regulation of Biotechnology (the "Coordinated Framework" or "Framework") provides some regulatory cover for microorganisms.[40] Established during the 1980's under the Reagan administration, the Coordinated Framework rests on the premise that existing statutes would provide sufficient regulatory authority to manage the emerging set of biotechnology products.[41] The Framework grew out of a concern that genetic engineering techniques would "pose greater risks than those achieved through traditional manipulation techniques."[42] As such, it focused on a collection of existing regulations that would primarily govern genetically engineered ("GE") organisms, and it attempted to distinguish genetically engineered organisms that required new federal oversight from naturally occurring ones that typically did not.[43] Still, many of the statutes and regulations that make up the Coordinated Framework apply equally to GE as well as naturally occurring microorganisms.[44]

The Coordinated Framework splits regulatory authority among three separate agencies: the Environmental Protection Agency ("EPA"), the FDA, and the Animal and Plant Health Inspection Service ("APHIS") under the United States

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[40] *See generally* Chris A. Wozniak et al., *An Introduction to Agricultural Biotechnology Regulation in the U.S., in* REGULATION OF AGRICULTURAL BIOTECHNOLOGY: THE UNITED STATES AND CANADA (Chris A. Wozniak & Alan McHughen eds., 2013) [hereinafter *Introduction to Biotechnology Regulation*] (providing an overview of biotechnology regulation along with application of the regulations to microbes).

[41] Chris A. Wozniak et al., *Regulation of Genetically Engineered Microorganisms Under FIFRA, FFDCA and TSCA, in* REGULATION OF AGRICULTURAL BIOTECHNOLOGY: THE UNITED STATES AND CANADA 59, 59 (Chris A. Wozniak & Alan McHughen eds., 2013) [hereinafter *Regulation of GE Microorganisms*].

[42] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 3 (proposed June 26, 1986) [hereinafter Coordinated Framework].

[43] *Id.* at 4 ("This framework has sought to distinguish between those organisms that require a certain level of federal review and those that do not. . . . Within agriculture, for example, introductions of new . . . microorganisms have long occurred routinely with only some of those that are not native or are pathogenic requiring regulatory approval. It should be noted that microorganisms play many essential and varied roles in agriculture and the environment and that for decades agricultural scientists have endeavored to exploit their advantages through routine experimentation and introduction into the environment; and as a rule these agricultural and environmental introductions have taken place without harm to the environment.").

[44] *See Introduction to Biotechnology Regulation*, *supra* note 40, at 3 (noting that non-GE microbial pesticides and GE microbial pest control agents are both regulated under FIFRA).

Department of Agriculture ("USDA").[45] The EPA derives authority from numerous statutes, including the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), the Toxic Substances Control Act ("TSCA"), and the Federal Food, Drug, and Cosmetic Act ("FD&C").[46] FIFRA provides mechanisms that allow the EPA to "[p]revent and eliminate unreasonable adverse effects" of pesticides and other related compounds, while TSCA authorizes the agency's regulation of toxic chemical substances.[47] The FD&C gives the EPA concurrent power to regulate pesticide residues in food.[48] The FD&C also gives broad authority to the FDA to regulate safety in human and animal food and drugs.[49] Finally, APHIS has authority to act under numerous statutes, most notably the Plant Protection Act ("PPA"), designed to protect agricultural plants and resources from plant pests and noxious weeds.[50]

Generally, due to the narrow scope of many of these statutes, microorganisms often do not fall within their purview. However, FIFRA and TSCA provide the basis for most regulatory coverage.

A. *FIFRA Overview*

FIFRA governs the regulation of pesticides generally.[51] It defines the term pesticide to include "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest" but expressly excludes any animal drug as defined by the FD&C.[52] Pests are also defined broadly as "any insect, rodent, nematode, fungus, weed" or "any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism [not living within a human or animal],"[53] which the EPA Administrator determines is injurious to health and the environment.[54] The statutory definition of pest could therefore theoretically encompass large swaths of the animal kingdom, including large mammals and birds. Likewise, pesticides would include any substances used to control this large category of organisms. Indeed, the regulations promulgated under FIFRA appear to focus more on the effect these "pests" may

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45 OFFICE OF SCI. & TECH. POLICY, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 8 (2017) [hereinafter 2017 FRAMEWORK UPDATE].

46 *Id.* at 9.

47 *Id.*

48 *Id.*

49 *Id.*

50 *Id.* at 9-10.

51 *See* Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y) (regulating "the marketing of economic poisons and devices").

52 7 U.S.C. § 136(u) (2012).

53 *Id.* § 136(t).

54 *Id.* § 136w(c)(1).

have on humans as their distinguishing characteristic, rather than narrowing the categories of organisms to which the expansive statutory definition applies. The current regulatory definition includes essentially all animals other than humans,[55] all plants, as long as they are growing "where not wanted,"[56] and "[a]ny fungus, bacterium, virus, prion, or other microorganism [except those living within humans or other animals or those already regulated in food under the FD&C]."[57] Perhaps because the list of possible substances subject to FIFRA regulation is so broad, EPA regulations expressly exclude or exempt numerous substances.[58] Among these excluded substances are "[p]roducts intended to aid the growth of desirable plants" including "[a] plant inoculant product consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system."[59] Recall the discussion of *Rhizobium*, *supra*, discovered in the 1800's. These microorganisms, which help plants uptake nitrogen and other nutrients from the soil, are expressly excluded from regulation under FIFRA. On the other hand, the regulations do expressly cover most other microorganisms used as pesticides.[60]

One key aspect of FIFRA's statutory power is the requirement to register any compound deemed a pesticide before it may be distributed or sold.[61] The EPA Administrator may, by regulation, limit the distribution or sale of any pesticide not registered "to prevent unreasonable adverse effects on the environment."[62] Registration procedures require entities to submit testing data along with the registration application to ensure the pesticide's effects are not unreasonably harmful.[63] The type of test data required depends on the type of pesticide

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55 *See* 40 C.F.R. §§ 152.5(a)-(b) (2018). 40 C.F.R § 152.5(a) covers all vertebrate animals with the exception of humans. 40 C.F.R § 152.5(b) covers all invertebrate animals.

56 *Id.* § 152.5(c).

57 *Id.* § 152.5(d).

58 The regulations both proactively exclude certain substances and provide for express exemptions. As a practical matter, it does not appear that there is any substantive difference between the two. For exclusions, *see id.* §§ 152.6 (substances expressly excluded from regulation such as sterilants or animal drugs), 152.8 (substances such as fertilizer or products intended to force bees from hives for the purposes of collecting honey because they are "not for use against pests"), and 152.10 (substances such as deodorizers or pruning paints on trees that are not intended for a "pesticidal purpose"). For exemptions, *see id.* §§ 152.20 (Exemptions for Pesticides Adequately Controlled by Another Federal Agency), 152.25 (Exemptions for Pesticides of a Character Not Requiring FIFRA Regulation), and 152.30 (Pesticides that May Be Transferred, Sold, or Distributed Without Registration).

59 *Id.* § 152.6(g)(2).

60 *See id.* § 152.20(a)(1), (3) (providing that "all biological control agents are exempt from FIFRA requirements" with the exception of eukaryotic and prokaryotic microorganisms and "parasitically-replicating microscopic element[s], including, but not limited to, viruses.").

61 7 U.S.C. § 136a(a) (2012).

62 *Id.*

63 *Id.* § 136a(c)(2)(A).

registered, and regulations governing this data are quite extensive.[64]

Despite extensive regulations governing registration and testing for various classes of pesticides, FIFRA does allow for use of unregistered pesticides under an Experimental Use Permit ("EUP").[65] The Administrator may grant an EUP "only if the Administrator determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide . . . ."[66] Since 2011, for example, the EPA has granted EUPs to numerous entities for the purpose of releasing *Wolbachia*-infected mosquitos.[67]

B. *TSCA Overview*

When originally enacted in 1976, Congress intended TSCA to close the regulatory gaps for chemical substances that were not already regulated as pesticides under FIFRA or food additives, pesticide residue, or drugs under the FD&C.[68] Section five of TSCA contains key provisions applicable to microorganisms and new chemical substances. No person may manufacture a new chemical or manufacture or process an existing chemical substance in a significantly new way without first notifying the EPA through a premanufacture notification ("PMN").[69] EPA regulations refer to the PMN required for microorganisms as a Microbial Commercial Activity Notice (MCAN).[70] Classification of a chemical as "new" depends on whether the chemical is listed on the TSCA Chemical Substance Inventory (the "Inventory") established by section 8(b) of the act.[71] Similar to the far-reaching definition of pesticide in FIFRA, TSCA defines chemical substance to include "any organic or inorganic substance of a particular molecular identity."[72] This definition includes "any combination of such substances occurring in whole or in part as a result of a

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64 *See Pesticide Registration Manual: Chapter 2 – Registering a Pesticide Product*, ENVTL. PROTECTION AGENCY, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product (last updated Apr. 20, 2017), (establishing three categories of pesticides with different requirements for each – conventional (chemical) pesticides, biopesticides, and antimicrobial pesticides). Regulations stipulate requirements for microorganism pesticide testing in chapter 40, part 158, subpart V of the Code of Federal Regulations. *See* 40 C.F.R. §§ 158.2100-2174.

65 7 U.S.C. § 136c (2012).

66 *Id.* § 136c(a).

67 *See* Stephen L. Dobson et al., Wolbachia *Mosquito Control: Regulated*, 352 SCI. 526 (Apr. 28, 2016).

68 *See* S. Rep. No. 94-698, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4491 ("While certain environmental health statutes may be used to protect health and the environment from chemical substances, only pesticides, drugs, and food additives undergo premarket scrutiny prior to first manufacture. . . . While air and water laws authorize limitations on discharges and emissions, . . . there are no existing statutes which authorize the direct control of industrial chemicals themselves for their health or environmental effect.").

69 15 U.S.C. §§ 2604(a)(1)(i)-(ii), 2604(a)(1)(B) (2012).

70 *See* 40 C.F.R. § 725.100(a) (2018).

71 15 U.S.C. § 2602(11) (2012).

72 *Id.* § 2602(2)(A).

chemical reaction or occurring in nature."[73] Thus, as long as the chemical substance is not already included as part of the Inventory, section five requirements likely apply.

The EPA has interpreted the definition of "chemical substance" quite broadly. With regard to TSCA's coverage of microorganisms, for example, during the initial rule making process in 1977, the EPA received a comment that stated, "[c]ommercial biological preparations such as yeasts, bacteria, and fungi should not be considered 'chemical substances' under TSCA."[74] The EPA disagreed, stating:

> The Administrator disagrees with this comment. The term chemical substance is defined to mean 'any organic or inorganic substance of a particular molecular identity including any combination . . . occurring in nature.' This definition does not exclude life forms which may be manufactured for commercial purposes and nothing in the legislative history would suggest otherwise.75

Thus, the EPA considers microorganisms not intended for use as pesticides to be subject to the requirements of TSCA.

As mentioned, entities may still manufacture, distribute, or sell a "new" chemical substance not listed on the Inventory by submitting a PMN to the EPA.[76] Manufacturers must submit any available health and safety data available to them at the time they submit the PMN; however, there is no requirement that the manufacturer develop such data.[77]

The PMN process triggers a number of actions. Prior to the 2016 amendments to TSCA, the EPA had ninety days after the submission of a PMN to determine if the chemical substance was safe for manufacture or distribution or whether to require additional testing data.[78] In the absence of any EPA determination, manufacturers could proceed.[79]

However, the 2016 amendments to TSCA changed this approach dramatically. The current statute bars manufacture of new chemicals even after the ninety-day window if the EPA has not conducted a review of the PMN and made one of three specific findings. The EPA must determine that (A) the new chemical substance or significant new use of a chemical substance presents an unreasonable risk to human health or the environment; (B) there is insufficient

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73 *Id.* § 2602(2)(A)(i).

74 42 Fed. Reg. 64,542, 64,584-85, comment 30 (Dec. 23, 1977).

75 *Id.*

76 15 U.S.C § 2604(a)(1)(B) (2012).

77 15 U.S.C. §§ 2604(d)(1)(B)-(C).

78 *See* Toxic Substances Control Act of 1976, Pub. L. No. 94–469, § 5(a)(1)(B), 90 Stat. 2003 (barring the manufacture of "new" chemical substances or significant new uses of substances unless (1) a PMN was submitted ninety days prior and (2) the EPA Administrator did not require submission of testing data as required under section (b)).

79 *Id.*

information available for the EPA Administrator to make a determination of the risks posed by the chemical substance; or (C) the chemical substance is not likely to pose unreasonable risk to human health or the environment.[80] If the EPA Administrator determines that insufficient information exists to assess risk, the Administrator must issue an order that prohibits or limits the "manufacture, processing, distribution in commerce, use, or disposal of such [chemical substance]" to the extent the Administrator deems necessary to protect against unreasonable risk to human health or the environment.[81] Entities may then proceed with their planned activity as long as it is in compliance with the EPA's order.[82]

The Inventory includes both specific chemical substances explicitly listed by the EPA[83] as well as entire classes of substances that the EPA may designate as part of the Inventory (and thus exempt from the PMN requirements of the statute) by regulation. Related to microorganisms, for example, the EPA has designated that only microorganisms that are "manufactured, imported, or processed for commercial purposes" are subject to TSCA regulations.[84] In addition, the EPA has grandfathered all non-intergeneric microorganisms by automatically including them as part of the Inventory.[85] The EPA defines "intergeneric microorganism" as those "formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera."[86] This definition covers those microorganisms that have been genetically engineered to include genetic material from a different genus from the microorganism, but excludes GE microorganisms with genetic material from "well-characterized, non-coding regulatory regions from another genus."[87] Through these regulations, the EPA has specifically focused the application of TSCA on GE microorganisms (and then only for a specific class of genetic engineering), and it has excluded those that are naturally occurring from TSCA's coverage. In addition, the EPA has excluded any non-commercial use of microorganisms, including non-commercial uses of GE microorganisms.

While section five excludes substances that are part of the Inventory from notification requirements, sections four and six ostensibly give the EPA specific powers to regulate any substance, including those in the Inventory.[88] Section

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80 15 U.S.C. § 2604(a)(3)(A)-(C).

81 *Id.* § 2604(e).

82 *Id.*

83 *See, e.g.*, *Substance Registry Service (SRS)*, ENVTL. PROTECTION AGENCY, https://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/searchbylist/search.do (last updated Aug. 23, 2017). This list includes only the non-confidential substances that the public may see.

84 40 C.F.R. § 725.8(a) (2018).

85 *Id.* § 725.8(b).

86 *Id.* § 725.3.

87 *Id.*

88 *See* 15 U.S.C. §§ 2603(a)(1)(A)(i)(I), 2603(a)(1)(A)(ii)(I) (2012) (authorizing the EPA to act generally with regard to "a chemical substance," absent an express modifier restricting coverage to *new* chemical substances). *See also* 15 U.S.C § 2605(a) (similarly defining the scope to cover "a

four allows the EPA to require testing of two classes of substances. First, if the EPA determines it cannot reasonably determine the effects of a chemical substance, and that the substance may present unreasonable risk to health or the environment, then the agency may by rule, order, or consent agreement require testing of the substance, if it finds that testing is necessary to develop adequate health and safety data.[89] In addition, the EPA may also require the development of health and safety data for any substance it finds will enter the environment in significant quantities or to which humans may have significant or substantial exposure.[90] The EPA may require testing of this second category of substances without considering whether the substance may present an unreasonable risk to health or the environment.[91] However, the agency may only subject handlers of this second class of substances to testing requirements after complying with rule making requirements.[92]

Section six of TSCA grants the EPA a number of additional enumerated powers to regulate chemical substances.[93] These powers include authority to prohibit or restrict manufacture, processing, or distribution in commerce of a chemical substance generally or for a particular use,[94] authority to require labeling,[95] and the power to require manufacturers or processors to maintain records of their handling of a substance,[96] among others. The 2016 TSCA amendments substantially altered the law regarding these enumerated powers. Prior to the amendments, the EPA could only exercise those powers that were "least burdensome," and only if it found the substance presented an unreasonable risk to health or the environment.[97] The amendments removed the "least burdensome" language from the statute.[98] In addition, though TSCA still requires the EPA to assess whether the chemical substance risk is "unreasonable" before the agency can impose any section six requirements on manufacturers or processors,[99] the 2016 amendments separate risk assessment from risk management. TSCA now requires the EPA to perform risk

chemical substance").

89 *Id.* § 2603(a)(1)(A)(i).

90 *Id.* § 2603(a)(1)(A)(ii).

91 *Id.*

92 *Id.* § 2603(a). The Administrative Procedure Act lays out procedural requirements most agencies must follow when engaging in rule making. The rule making may require a formal agency hearing. *See* 5 U.S.C. §§ 556-57 (2012). Alternatively, an agency may promulgate rules informally. *See id.* § 553. The informal rule making process requires publication of the proposed rule in the Federal Register, followed by a comment period where "interested persons" have an opportunity to submit "written data, views, or arguments . . ." *Id.* § 553(b)-(c). The agency must then consider these comments before issuing a final rule. *Id.* § 553(c)-(d). Even informal rule making can therefore consume a fair amount of time and agency resources.

93 *See* 15 U.S.C. §§ 2605(a)(1)-(7).

94 *Id.* § 2605(a)(1)-(2).

95 *Id.* § 2605(a)(3).

96 *Id.* § 2605(a)(4).

97 *See* Toxic Substances Control Act of 1976, Pub. L. No. 94–469, § 6(a), 90 Stat. 2003.

98 *See* 15 U.S.C. § 2605(a).

99 *Id.*

assessments, without regard to costs,[100] on ten specific chemicals within 180 days after passage of the amendments, on at least twenty additional "high-priority substances" within three and a half years, and on other substances "at a pace consistent [with statutorily defined deadlines]."[101] So, while the EPA may not exercise section six authority over a chemical substance without performing a risk assessment,[102] the statue directs the EPA to actually perform those assessments on a specific schedule.

III. GAPS IN THE EXISTING REGULATORY SCHEME

FIFRA and TSCA contain numerous gaps in their coverage of microorganisms, some perhaps more obvious from the discussion above, and some more subtle. The discussion below details these gaps and analyzes the extent to which these statutes regulate the specific microorganisms highlighted earlier in the article.

A. *FIFRA Gaps*

While the language of FIFRA appears to grant the EPA wide-ranging authority to regulate any number of substances it may classify as pesticides, the agency may only regulate pesticides "to prevent unreasonable adverse effects on the environment."[103] Courts have interpreted this language to require the EPA to engage in a cost-benefit analysis, balancing economic, social, and environmental costs against the benefits of the pesticide.[104] When the risks are largely unknown, however, such balancing is difficult.[105] This may lead regulators to miss important risk profiles of a candidate pesticide, tipping the scale of the cost-benefit analysis more towards the beneficial uses of the pesticide and ultimately favoring approval of the registration application.[106] Thus, because so much of the science with respect to microorganisms and indeed many emerging technologies is still developing, statutes such as FIFRA are less effective at regulating such substances than may be apparent at first glance.[107]

B. *TSCA Gaps*

With regard to TSCA, the gaps in the statutory and regulatory coverage of microorganism usage are more obvious. As previously indicated, TSCA

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100 *Id.* § 2605(b)(4)(A).

101 *Id.* § 2605(b)(2)(A)-(C).

102 *Id.* § 2605(a).

103 7 U.S.C. § 136a(a) (2012).

104 ALBERT C. LIN, PROMETHEUS REIMAGINED: TECHNOLOGY, ENVIRONMENT, AND LAW IN THE TWENTY-FIRST CENTURY 61 (2017); *see also* 7 U.S.C. § 136(bb).

105 LIN, *supra* note 104.

106 *Id.*

107 *Id.*

regulations expressly exclude from section five jurisdiction all microorganisms that are not intergeneric.[108] Thus, despite the broad reach of the statute to regulate chemical substances, including microorganisms, the EPA has chosen to exclude all microorganisms from notification requirements unless they are genetically altered in specific ways.[109] In addition, the EPA has chosen to focus on commercial applications of microorganisms.[110] The emphasis on commercial use may allow the EPA to focus their limited resources on those applications they deem to pose the greatest risk. Still, TSCA section five leaves unregulated any research at an academic institution or any private use of microorganisms.[111] Moreover, even though TSCA regulates most GE microorganisms, the fact that it leaves out non-commercial applications means that many of the Do-It-Yourself ("DIY") synthetic biology kits[112] emerging on the market that allow novel genetic modifications to bacteria or other microorganisms would escape regulation. As a result, many cases of extensively modified organisms could potentially remain unregulated.

TSCA also contains significant gaps for those intergeneric GE microorganisms developed for commercial use that are ostensibly subject to section five requirements. Because the EPA has interpreted TSCA only to cover intergeneric genetically modified ("GM") microorganisms, newly developed synthetic biology techniques used to modify microorganisms may entirely escape regulation.[113] For example, with some synthetic biology techniques, novel gene sequences that do not exist anywhere in nature may be added to a microorganism.[114] Alternatively, modern gene editing technology allows removal of gene fragments, or modification of an existing fragment, and reinsertion back into the same organism.[115] None of these techniques would qualify under TSCA's definition of intergeneric, since such newly inserted gene sequences (or those that were removed) would not be isolated from microorganisms of a different genus.[116]

Thus far, the discussion has focused on limits imposed by TSCA regulations that allow large classes of microorganisms to escape notification requirements. However, even if a particular microorganism were deemed "new" under TSCA, the act suffers from the same difficulties with regard to cost-benefit analysis as does FIFRA. First, manufacturers need not submit health and safety data with

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108 *See supra* text accompanying note 85.

109 *See supra* text accompanying notes 85-87.

110 *See supra* text accompanying note 84.

111 *See* BERGESON ET AL., *supra* note 27, at 31.

112 *See, e.g.*, *DIY Bacterial Gene Engineering CRISPR Kit*, THE ODIN, http://www.the-odin.com/diy-crispr-kit (last visited Nov. 5, 2017).

113 BERGESON ET AL., *supra* note 27, at 32.

114 *Id.*

115 *Id.*

116 *Id.*

the PMN unless such data is known to them.[117] The EPA may require testing of the chemical substance under section four, but only if the EPA Administrator finds there is insufficient information to predict chemical effects and that the substance may present unreasonable risk to human health or the environment.[118] Thus, TSCA may incentivize manufacturers or distributors of microorganisms that are potentially subject to EPA-mandated testing to forgo gathering any health and safety data on their own, so that they are not required to disclose it. In addition, the "unreasonable risk" language of the statute requires at least some balancing of the environmental costs against the potential benefits of using the microorganism.[119] When the risks of deployment of microorganisms in the environment are largely unknown, however, this cost-benefit analysis presents an obstacle to EPA-mandated testing. Finally, while the 2016 section six amendments mandate risk assessments and reduce some barriers to section six enforcement,[120] the section ultimately requires similar "unreasonable risk" cost-benefit balancing that plagues TSCA section four and FIFRA before the EPA can exercise any of its section six enumerated powers.[121]

C. *Regulation in the Real World*

It is instructive to look at the real-world applications of microorganisms discussed at the beginning of this article and consider to what extent they may be covered by existing regulations. Two of the applications involve the use of bacteria to enhance plant health. *Rhizobium*, the bacterium that promotes more efficient nitrogen capture in the roots of leguminous plants, is not subject to TSCA notification requirements because it is not intergeneric. The same is true for *Rhizobium etli*, the bacterium scientists in Mexico believe could someday eliminate the need for GM drought-resistant plants.[122] Both bacteria are therefore included on the Inventory automatically and not subject to MCAN requirements. The EPA could require testing if health and safety data does not exist for either bacteria. However, the EPA would first need to weigh costs against potential benefits of the bacteria and show that they may pose "unreasonable risk" to human health or the environment.[123] Alternatively, the EPA could require testing, without regard to costs, if it finds either bacteria is produced in large quantities or that it may have substantial or significant human exposure.[124] However, any testing requirements the EPA imposes under this scenario would require the agency to engage in the (usually lengthy) rule

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117 15 U.S.C. § 2604(d)(1)(B)-(C) (2012).

118 *Id.* § 2603(a)(1)(A).

119 *See* LIN, *supra* note 104.

120 *See supra* text accompanying notes 98-102.

121 *See* 15 U.S.C. § 2605(a).

122 *See supra* text accompanying note 10.

123 *See supra* text accompanying note 118.

124 *See supra* text accompanying notes 90-91.

making process.[125] Under TSCA section six, the EPA could mandate labeling or record maintenance requirements, or the agency could restrict or prohibit use of either bacteria.[126] Even here, however, the EPA would first need to perform a risk assessment of the bacteria and find that the costs outweigh the benefits before exercising any of its section six statutory powers.[127]

Looking at FIFRA's regulatory coverage of the two microorganisms targeted at plant health, as noted, *Rhizobium* has been expressly excluded from FIFRA jurisdiction.[128] *Rhizobium etli* also does not appear to fall within FIFRA's jurisdiction, since its purpose is not to combat anything that would be deemed a pest under the definition of the statute. Thus, barring a finding by the EPA that costs outweigh benefits, and absent other EPA-imposed (by rule only) section six requirements, it appears that both types of bacteria may largely escape regulation altogether.

Turning to the *Salmonella*-inhibiting bacteria *Paenibacillus alvei*, again, TSCA would not apply since this microorganism appears to be naturally occurring in the soil of West Coast tomato plants.[129] Scientists are simply trying to isolate these bacteria so that they can use them in other applications. The definition of pest, as defined by FIFRA regulations, would likely apply to this situation, since the definition includes bacteria.[130] FIFRA's definition of pesticide would likely apply here as well, since the definition covers any substance designed to prevent, destroy, or mitigate a pest.[131] Thus, this application would likely qualify for regulation under FIFRA.

Before determining whether to impose restrictions on the use of *Paenibacillus alvei* under FIFRA, however, the EPA must weigh potential environmental costs against the bacteria's purported benefits.[132] The benefits are obvious. The entire purpose of doing this research is to potentially reduce the severity and frequency of food borne illness resulting from *Salmonella* contamination of tomatoes. History has shown that outbreaks of *Salmonella* poisoning from tomatoes occurs on the East Coast approximately twice a year affecting ten to one hundred people.[133] For most people, the impact is not severe, but for the very old or very young, infections may result in hospitalization or death.[134] The costs are harder to quantify. On the one hand, the fact that these bacteria exist already in the soil of most West Coast tomato plants provides a strong argument that the

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125 *See supra* text accompanying note 92.

126 *See supra* text accompanying notes 93-96.

127 *See supra* text accompanying notes 97, 98.

128 *See supra* text accompanying note 59.

129 Thus, it is not intergeneric. *See supra* text accompanying note 86.

130 *See* 40 C.F.R. § 152.5(d).

131 *See* 7 U.S.C. § 136(u) (2012).

132 *See supra* text accompanying note 104.

133 Conniff, *supra* note 7.

134 *Id.*

environmental costs of spraying *Paenibacillus alvei* on other plants is negligible. After all, millions of Americans eat tomatoes grown on the West Coast without harmful side effects. On the other hand, however, the interaction of this bacteria with other bacteria that may be present on East Coast tomato plants is largely unknown. There may be unforeseen side effects of the bacteria when applied to East Coast plants. Furthermore, the concentration of the bacterial solution used may be different from what naturally occurs. In short, any number of variables may be different or unknown, giving rise to the potential for unforeseen consequences. These unknowns could ultimately lead to an underrepresentation of the risks associated with the use of the bacteria, nudging the EPA to waive registration and testing requirements.

Wolbachia use on *Aedes aegypti* mosquitoes falls squarely within the realm of FIFRA. *Aedes aegypti* mosquitoes are in some ways prototypical pests, and the EPA would consider any substance used to control them an insecticide. Thus far, it appears that most deployments of *Wolbachia* in mosquitos have been exempted from registration and testing through the use of EUPs.[135] Note, however, the EPA Administrator may only grant EUPs if the permit helps applicants gather more data on health and safety aspects of the pesticide.[136] At some point, presumably, such data will be known, and the EPA will move on to determining whether formal registration procedures and use restrictions apply. When that happens, the EPA must determine whether the use of the bacteria poses an unreasonable risk to the environment.[137] Here, it is notable that there is some debate in the community as to the potential risks of commercial *Wolbachia* use. Some have noted that scientists have not adequately considered the possibility that the bacteria might transfer horizontally to other hosts, leading to unpredictable side effects.[138] Others have countered that horizontal transfer is considered rare, and that of the three to eight million species of insect on the planet, *Wolbachia* is estimated to be naturally present in half of them.[139] Thus, any risks associated with *Wolbachia* use are overblown.[140]

Finally, turning to the innovative use of bacteria to aid in copper extraction, to the extent that Universal BioMining plans to use naturally occurring bacteria to aid in the process, such bacteria would escape TSCA jurisdiction, similar to all of the other examples discussed previously. However, the company has also considered genetically altering the bacteria using synthetic biology techniques to make them more efficient at extracting copper from the mined rock.[141] Such

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135 *See* Dobson, *supra* note 67, at 526.

136 7 U.S.C. § 136c(a) (2012).

137 *Id.* § 136a(c)(2)(A).

138 Elgion Lucio Silva Loreto & Gabriel Luz Wallau, *Risks of* Wolbachia *Mosquito Control*, 351 SCI. 1273 (Mar. 18, 2016).

139 Scott L. O'Neill, Wolbachia *Mosquito Control: Tested*, 352 SCI. 526 (Apr. 29, 2016).

140 *Id.*

141 BERGESON ET AL., *supra* note 27, at 36.

techniques may allow the EPA to require a MCAN and possibly subject the company to testing requirements under TSCA before the company could move forward with the process. However, even here, there are questions. It is not entirely clear how the company plans to modify the bacteria. If the modifications they make fall outside the definition of intergeneric, they may escape regulation.[142] Even if the EPA requires a MCAN before allowing the company to proceed with deployment, it is worth noting that the EPA has allowed ninety-five percent of intergeneric microorganisms that have been subject to premanufacture notification (i.e., MCANs) to proceed to market without restriction.[143]

In summary, these real-world applications of microorganisms comprise an extremely small sample size. However, applying existing statutes and regulations to these examples provides insight into how the statutes function in reality while highlighting their gaps. FIFRA does provide a hook to capture most applications that are pesticide-like in nature. This includes the use of *Wolbachia* in mosquitos, and likely the use of *Paenibacillus alvei* on tomato plants. However, as discussed, engaging in the cost-benefit analysis as required by FIFRA may lead the EPA to discount registration and testing requirements. As for TSCA, section five covers almost none of the applications discussed here because of its express exemption for naturally occurring bacteria. In addition, section five's coverage of GE microorganisms is limited to commercial applications that fall within the narrow definition specified in the statute, allowing many applications to escape regulation. For those microorganisms subject to notification, testing, or other section six requirements, the EPA so far has seemed reluctant to require additional restrictions on their use.

IV. TAKEAWAYS FROM OTHER TYPES OF ENVIRONMENTAL REGULATION

The statutory framework that exists today only provides partial coverage for the range of contemplated applications of microorganisms. This begs the question, therefore, whether we can do better. To help with that investigation, it is useful to look at lessons that we may glean from other types of environmental regulation.

A. *Ex Ante Regulation: GM Plants and Animals*

The regulation of GMOs presents an interesting case study that elicits some of the problems with *ex ante* regulation of emerging technologies. Though the Coordinated Framework provides some coverage for regulation of microorganisms, it was primarily developed as a mechanism to regulate

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142 See BERGESON ET AL., *supra* note 27, at 35-38, for an excellent and much more thorough discussion of this use case.

143 *Id.* at 38.

GMOs.[144] The difference in how the Framework regulates GM plants and GM animals provides an instructive contrast. For GM plants, the Coordinated Framework is decidedly and consciously product based. It focuses first and foremost on regulation of biotechnology products, not on the process by which those products are made.[145] The decision to regulate GM plants in this way has left many gaps. First, APHIS's jurisdiction to regulate GM plants through the PPA is limited.[146] The PPA allows APHIS to regulate GM plants to the extent that the GM plant itself is a pest, or to the extent that the DNA sequences used in modification come from plant pests.[147] However, the ability for APHIS to regulate such modified species will likely become increasingly more limited.[148] This is especially true with the advent of synthetic biology techniques that create novel sequences in plants not found elsewhere in nature or that remove DNA segments from the plants.[149]

The FDA's regulatory authority under the FD&C is similarly spotty.[150] The FDA derives authority under the FD&C to regulate GM plants under its power to regulate food additives.[151] The statute allows the FDA to subject food additives to premarket approval.[152] However, foods generally recognized as safe ("GRAS") are exempted from such premarket approval.[153] With regard to modification of GM plants, the FDA has generally chosen to view these modifications as GRAS, thus effectively removing GM plants from any regulatory oversight under the FD&C.[154]

The EPA may regulate GM plants under FIFRA (for plants genetically engineered to produce pesticides, known as plant incorporated protectants ["PIPs"]) and under the FD&C (for pesticide residue on food).[155] FIFRA faces similar challenges in regulating PIPs, however, as it does with microorganisms. In evaluating whether to grant registration of a new PIP, the EPA must engage

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144 *See* Coordinated Framework, *supra* note 42.

145 *See* 1992 Update to the Coordinated Framework, 57 Fed. Reg. 6,753 (Feb. 27, 1992) ("It [the Coordinated Framework] . . . focuses on the characteristics of the *biotechnology product* and the environment into which it is being introduced, not the *process* by which the product is created.") (emphasis added).

146 LIN, *supra* note 104, at 57.

147 *Id.*

148 *Id.*

149 *Id.*; *see also* NAT'L ACAD. OF SCIENCES, PREPARING FOR THE FUTURE OF BIOTECHNOLOGY 28 (2017) (discussing new trends in synthetic biotechnology that allow insertions, deletions, and whole DNA sequences to be built from scratch).

150 *See* LIN, *supra* note 104, at 59.

151 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,989-90 (May 29, 1992) [hereinafter "FDA Policy on GM Plants"].

152 *Id.* at 22,989.

153 *Id.*

154 *Id.* at 22,990 ("With respect to transferred genetic material (nucleic acids), generally FDA does not anticipate that transferred genetic material would itself be subject to food additive regulation.").

155 LIN, *supra* note 104, at 60.

in the same cost-benefit analysis that makes it difficult to evaluate microorganisms.[156] As with many emerging technologies where risks are largely unknown, this analysis may undervalue the costs of the PIP in favor of benefits, requiring the EPA to approve the registration.[157]

As with regulation of microorganisms under FIFRA and TSCA, regulation of GM plants under the Coordinated Framework may fairly be described as "questionable" providing "little valuable oversight."[158] Though the focus on product-based regulation was deliberate, history has shown that the patchwork approach exemplified by the Framework leaves numerous holes. Existing statutes have been stretched to cover new use cases. APHIS derives authority to regulate GM plants as plant pests if the specific donor organism or vector used to inject DNA into the recipient plant is classified as a plant pest.[159] The FDA views any DNA added to a GM plant that may ultimately be consumed as food as a food additive, and thus subject to FD&C regulations.[160] The EPA views GM plants engineered to express pesticides as PIPs, and thus subject to FIFRA requirements.[161]

Yet, new synthetic biology techniques that don't involve plant pest donors or vectors allow GM plants to escape the narrow jurisdictional hook that APHIS uses to regulate GM plants. In addition, there is ample evidence that even when given authority to regulate under the PPA, APHIS tends to avoid substantive oversight.[162] The FDA seems to regard the similarity of GM plants to their non-GM cousins as well as the pervasiveness of GM plants and the apparent lack of adverse effects on human health as justification for treating GM plants as GRAS.[163] While the EPA may be more willing to regulate the pesticidal aspects of GM plants, it appears hampered by the same statutes that make it difficult to regulate some microorganisms as pesticides.[164] The EPA also has limited authority to regulate GM plants outside of the context of pesticides or pesticide residue in food.

All of these issues point to two main takeaways with regard to the regulation of GM plants: (1) a regulatory structure that calls for regulation of products will necessarily be limited as products change and the statutory authority given to

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156 *Id.* at 61.

157 *Id.*

158 *Id.* at 55.

159 2017 FRAMEWORK UPDATE, *supra* note 45, at 24.

160 FDA Policy on GM Plants, *supra* note 151.

161 LIN, *supra* note 104, at 60.

162 *See* LIN, *supra* note 104, at 57-59 (noting that APHIS focuses more on risk to agriculture than it does on risk to the environment, that APHIS typically allows GM plants to proceed with field tests under a notification process rather than the stricter permitting process, and that APHIS regularly deregulates GM crops prior to widespread commercialization).

163 *See supra* text accompanying note 154.

164 *See supra* text accompanying notes 104-107 (discussing the challenges of performing a cost-benefit analysis on emerging technologies).

agencies is not able to evolve quickly enough to match the changing nature of the technology; and (2) when risks are unknown, regulators may not use the statutory authority given to them to regulate emerging technologies. This becomes even more difficult when the relevant statutory authority requires them to weigh uncertain environmental, social, and economic costs against purported benefits of using the technology.

Remarkably, the approach taken towards GM animals stands in stark contrast to that for GM plants. Rather than jerry-rig existing statutes based on the characteristics and purposes of largely finished products, the government has turned to a process-based approach to regulate GM animals. The FDA has issued industry guidance indicating that it plans to regulate GM animals as an animal drug under the FD&C.[165] The guidance expressly discusses modern genome editing techniques[166] and considers each alteration (whether it is an insertion, deletion, or modification) as a separate new animal drug.[167] In contrast to the FDA's stance on GM plants where it premises modifications to plants as GRAS, and thus generally exempts them from regulation, the FDA subjects animal drugs to much more stringent requirements.[168] New animal drugs are "deemed unsafe" under the FD&C unless the FDA has approved a new animal drug application ("NADA") for the drug or unless the FDA exempts the drug under an Investigational New Animal Drug ("INAD") exemption.[169] No analysis is required to determine which agency or which statute applies. The agency may impose stringent requirements on the entire industry because FDA's interpretation of its statutory authority enables it to exercise jurisdiction over almost any GM animal modified under a broad range of processes. At the same time, the agency appears more reluctant to grant exemptions to statutory requirements for GM animals than it does for GM plants. Though GM salmon have been commercially viable since 1995,[170] the FDA did not approve the NADA for GM salmon until twenty years later in 2015.[171] To date, this is the only GM animal the FDA has approved.

The contrasting approaches taken towards GM plants and GM animals reveal problems with both. On the one hand, a product-based approach, such as that taken towards GM plants and microorganisms, leaves many holes and gaps. It

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165 U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE #187: GUIDANCE FOR INDUSTRY REGULATION OF INTENTIONALLY ALTERED GENOMIC DNA IN ANIMALS 6 (2017) [hereinafter "FDA DRAFT GUIDANCE FOR INDUSTRY"].

166 *See id.* at 4.

167 *Id.* at 7.

168 *See id.* at 6-7.

169 *Id.* at 6.

170 *See* Margaret Rosso Grossman, *Genetically Engineered Animals in the United States: The AquAdvantage Salmon*, 11 EUR. FOOD & FEED L. REV. 190, 193 (2016) (noting that AquaBounty applied for approval of its GM salmon in 1995).

171 *See* Bernadette M. Dunham, *AquAdvantage Salmon Approval Letter and Appendix*, U.S. FOOD & DRUG ADMIN. (Nov. 19, 2015), https://www.fda.gov/AnimalVeterinary/ucm466214.htm.

faces challenges in coverage as emerging technologies rapidly evolve. In addition, when given authority to regulate, agencies appear reluctant to exercise their authority, possibly out of fear of hindering innovation or because they genuinely cannot assess risks of the technology when so much is unknown. On the other hand, if the underlying statute allows regulation of a broad set of processes, as is the case with GM animals, agencies retain much greater control over the technology. This in turn may lead risk-averse agencies to effectively block entire industries.

We can rightly criticize the agencies with jurisdiction over either technology. But perhaps the problem is that agencies have been given an impossible task. With respect to current microorganism regulations, it seems unconscionable that the EPA should exclude from regulation so many of the current applications that involve naturally occurring microorganisms. However, it also seems reasonable that the EPA might decline to regulate this class of microorganisms, given the difficulties in evaluating risk and statutory mandates to balance those risks against the microorganism's benefits. Indeed, scientists have made reasonable arguments regarding the safety of many of these applications.[172]

B. *Ex Post Liability*

If not the agencies, then perhaps the systems that govern agency behavior warrant more critical analysis. All of the regulatory schemes discussed thus far take an *ex ante* approach to prevent environmental harm by proscribing behavior before it occurs. As we have seen, when risk profiles are so uncertain, this approach may lead to under- or over-regulation. Numerous scholars have compared *ex ante* regulatory structures with systems that provide *ex post* remedies after harm occurs.[173] A closer look at aspects of *ex post* liability may lead to better insight into regulatory structures that could provide more effective governance of microorganisms.

The literature is replete with analyses of tort law through an economic lens.[174] Generally, these scholars cast the tort of negligence as an economically efficient means of reducing harm by encouraging safe behavior.[175] Captured famously by

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172 *See, e.g.*, *supra* text accompanying notes 139-140.

173 *See, e.g.*, Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357 (1984) (identifying general "determinants" that may favor *ex ante* regulation over *ex post* liability and vice versa); Richard A. Epstein, *The Principles of Environmental Protection: The Case of Superfund*, 2 CATO J. 9, 14-16 (1982) (discussing *ex ante* and *ex post* remedies in the context of environmental protection).

174 For a brief history of tort law analysis from an economic perspective, see Gary T. Schwartz, *Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 TEX. L. REV. 1801, 1802-07 (1997).

175 *See* Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 33 (1972) ("Perhaps, then, the dominant function of the fault system is to generate rules of liability that if followed will bring about, at least approximately, the efficient – the cost-justified – level of accidents and safety.").

Learned Hand in *United States v. Carroll Towing Co.*, a party is liable when the probability of harm (P) times the gravity of harm caused (L) is greater than the burden of taking adequate precautions to prevent the harm (B).[176] Thus formulated, economically rational actors will exercise due care to prevent harm when the cost of prevention is less than cost of the harm itself.[177] Viewed from this perspective, perhaps the law of negligence could provide a better means to regulate emerging technologies such as microorganisms. Rational actors could self-regulate risky behavior, and spurred on by the deterrent effect of tort liability, efficiently draw the line where precautions no longer make good economic sense.

One wades into this debate with caution, however, as scholars do not universally extol the virtues of negligence law.[178] Courts have also been reluctant to require negligence in all settings. Instead, they have applied concepts of strict liability in situations such as the possession of wild animals, participation in ultra-hazardous activities, and products liability.[179] All of these settings involve the application of tort law to dangerous conditions.[180] Dangerous conditions include those that are inherently dangerous, such as the transportation of explosives or hazardous waste or the custody of wild or vicious animals, and those that are caused by placing a defective product on the market.[181] These situations call into question the deterrent effect of negligence law. They are characterized by something that is so volatile (i.e., explosives or wild animals) or so complicated (i.e., modern consumer products) that no amount of precaution or due care may adequately prevent harm from occurring in all cases.[182] Yet we are not satisfied that those who suffer harm, even absent fault by the defendant, have no recourse for compensation in these cases. Thus, courts have imposed strict liability regimes in these situations to address the harm victims have suffered.

Microorganisms, along with most emerging technologies, may fit more naturally into a strict liability framework for similar reasons. The risk of harm caused by many emerging technologies often evades quantification because so much about their risk is unknown. Thus, no amount of responsible behavior may

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176 United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).

177 Posner, *supra* note 175, at 32-33.

178 *Compare id.* (providing a quintessential law and economics analysis of negligence law), *with* Richard A. Epstein, *A Theory of Strict Liability*, 2 J. LEGAL STUD. 151 (1973) (arguing that causation, without regard to fault, should establish tort liability). Even scholars who advocate for a corrective justice rationale for tort law disagree amongst themselves. *See also* Schwartz, *supra* note 174, at 1811 n.77 (quoting one scholar as saying, "[there are] five [scholars] who believe in corrective justice and eighteen different analyses of what corrective justice is; and I am responsible for about ten of them, because I've changed my mind so many times.").

179 Charles E. Cantu, *Distinguishing the Concept of Strict Liability in Tort from Strict Products Liability: Medusa Unveiled*, 33 U. MEM. L. REV. 823, 827-28 (2003).

180 Epstein, *supra* note 178, at 177-79.

181 *Id.*

182 *Id.* at 185-86.

prevent harm. Moreover, just as complex consumer products with unforeseen manufacturing defects may cause harm, justifying application of strict liability standards, so too complex ecosystems may cause unforeseen behaviors in microorganisms that no amount of field-testing can adequately predict.[183] Therefore, no amount of due care in the handling of these technologies may prevent harm, the Learned Hand formula breaks down, and strict liability may be more appropriate.

Yet even absent a need to show fault, tort liability suffers from other problems, especially in the environmental context. To better understand these problems, it is useful to consider four factors that help determine when *ex post* liability may lead to better outcomes than *ex ante* regulation:[184] (1) whether individuals or regulators possess better knowledge about the risk factors involved in an activity,[185] (2) the ability of private actors to pay for the harm caused,[186] (3) the probability that responsible parties will face liability in tort,[187] and (4) the relative costs incurred by private parties in litigation or by the public in administration of a regulatory regime.[188]

In general, private actors will likely have more knowledge about risk factors and thus would more efficiently control their behavior under an *ex post* regime.[189] However, this need not always be true. In cases where research is required to better understand risk, for example, private parties may not have sufficient incentives to understand those risks.[190] In these cases, the government may commit public resources to the task and regulate accordingly.[191]

Looking to the second factor, relying solely on *ex post* liability schemes runs the risk that responsible parties may not have the ability to pay for the harm they cause.[192] Requiring insurance may mitigate these concerns, but even then, if the potential liability exceeds a private actor's assets, they may not have sufficient incentives to act safely.[193] In addition, in the context of emerging technologies, private insurers may not readily be able to assess risk, and thus may simply decide not to offer insurance at all.[194]

The third factor has proven especially challenging in the context of environmental torts. Establishing causation for environmental harms often proves difficult.[195] Inability to establish causation precludes liability in both a

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183 *See supra* text accompanying notes 33-35.

184 These factors come from the work of Professor Shavell, *supra* note 173.

185 *Id.* at 359.

186 *Id.* at 360.

187 *Id.* at 363.

188 *Id.*

189 *Id.* at 359-60.

190 *Id.* at 360.

191 *Id.*

192 *Id.*

193 *Id.* at 361.

194 *See generally id.*

195 Epstein, *supra* note 173, at 12 (noting problems of factual uncertainty in environmental

negligence and a strict liability system, allowing many environmental harms to go uncompensated.

Finally, the fourth factor may favor a liability scheme.[196] However, this conclusion may depend on the frequency of harm and the number of individuals harmed. *Ex post* liability will incur lower costs in general, if harm occurs relatively infrequently;[197] however, if large numbers of people are harmed, the practical costs of litigating a large number of cases may overwhelm the system.[198]

This discussion shows that usually the first and the fourth factors will favor *ex post* liability schemes, while the second and third factors generally favor *ex ante* regulation.[199] In practice, one may sensibly conclude that a combination of the two will lead to the most favorable outcome.[200]

C. *Combined Approaches: Hazardous Waste*

Given that a combination of *ex ante* regulation and *ex post* liability may lead to better outcomes, the law of hazardous waste can provide additional insight because it provides an example where the government has regulated using both approaches. The Resource Conservation and Recovery Act ("RCRA") sets out a "cradle to grave" tracking system for hazardous waste, with different regulatory requirements for each stage in the lifecycle of a hazardous substance.[201] In contrast, the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") retrospectively assigns liability to parties responsible for environmental damage *ex post*, when hazardous waste is released into the environment.[202]

CERCLA authorizes the federal government to implement cleanup activities related to any hazardous substance or any substance that the government deems an "imminent and substantial danger to the public health or welfare" released or threatened to be released into the environment.[203] The government may then hold any potentially responsible party ("PRP") liable for clean-up costs as well as for any "injury to, destruction of, or loss of natural resources" resulting from the release of the substance.[204] PRPs include a broad set of parties who have some connection to the hazardous substance, including the current owner or

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matters).

196 Shavell, *supra* note 173, at 364.

197 *Id.*

198 Epstein, *supra* note 173, at 16-17.

199 Shavell, *supra* note 173, at 365.

200 *See id.*

201 *Learn the Basics of Hazardous Waste*, ENVTL. PROT. AGENCY, https://www.epa.gov/hw/learn-basics-hazardous-waste (last updated Aug. 16, 2017).

202 CAROLINE N. BROUN & JAMES T. O'REILLY, RCRA AND SUPERFUND: A PRACTICE GUIDE § 9:1 (3d ed. 2017).

203 42 U.S.C. § 9604(a)(1).

204 *Id.* § 9607(a)(1)-(4).

operator of a facility,[205] any owner or operator of a facility at the time the hazardous substance was disposed of, anyone who arranged for disposal of the hazardous substance at the facility, and anyone who transported the substance to the facility.[206]

CERCLA strategically addresses several of the problems identified previously with *ex post* liability. First, CERCLA's liability provision assigns joint strict liability to all PRPs for all damages to natural resources and all remedial costs incurred by the government or private parties.[207] In addition, courts have interpreted the statute as establishing a much less stringent requirement on causation.[208] CERCLA does not require the government to show that the PRPs' actions caused the release of the hazardous substance into the environment. It simply requires the government to show that the environmental release of the substance injured or destroyed natural resources or led the government or a private party to incur cleanup costs, and that the liable party is related to that release by virtue of their categorization as a PRP.[209] Finally, to alleviate issues with the inability of private parties to pay for natural resource damages and cleanup costs, CERCLA established a Superfund with revenues from three separate sources – general revenues, a tax on crude oil imports and exports, and a tax on waste materials when transported to dumpsites.[210] These sources were supplemented by penalties and punitive damages assessed under the act.[211] Congress declined to re-authorize the Superfund in 1995, however, and the program was left to rely on existing funds and general revenues.[212] After existing funds ran out, cleanups have been paid for entirely out of general revenues.[213]

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205 The term "facility" is defined broadly to include almost any building, structure, or other type of location where hazardous waste has been "deposited, stored, disposed of, or placed, or otherwise come to be located." *Id.* § 9601(9).

206 *Id.* § 9607(a)(1)-(4).

207 *See id.* § 9607(a)(4)(A)-(C); Epstein, *supra* note 173, at 25-26. The statute does not expressly indicate it establishes strict liability or that no fault by PRPs is required before liability attaches; however, courts have interpreted CERCLA as a strict liability statute. *See, e.g.*, United States v. Mexico Feed & Seed Co., 980 F.2d 478, 484 (8th Cir. 1992) ("CERCLA is a remedial strict liability statute. As such, its focus is on responsibility, not culpability.").

208 *See, e.g.*, United States v. Alcan Aluminum Corp., 990 F.2d 711, 721 (2d Cir. 1993) ("[I]t seems plain that in addition to imposing a strict liability scheme, CERCLA does away with a causation requirement."); Niagara Mohawk Power Corp. v. Chevron U.S.A., Inc., 596 F.3d 112, 131 (2d Cir. 2010) ("The traditional tort concept of causation plays little or no role in the liability scheme.").

209 *Alcan Aluminum Corp.*, 990 F.2d at 721.

210 Epstein, *supra* note 173, at 32; *see also* Comprehensive Environmental Response, Compensation, and Liability Act of 1980, Pub. L. No. 96–510, §§ 211, 221 [hereinafter CERCLA of 1980].

211 Epstein, *supra* note 173, at 32; CERCLA of 1980, § 221(b)(1)(D)-(E).

212 KALEY BEINS & STEPHEN LESTER, SUPERFUND: POLLUTERS PAY SO CHILDREN CAN PLAY 10 (December 2015).

213 *Id.*

Despite its apparent virtues, however, CERCLA is not beyond reproach. While its strict liability provisions may be consistent with common law strict liability for hazardous substances, critics have noted several issues with the act's PRP provisions.[214] By holding so many parties liable for the cleanup of hazardous substances, the act dilutes incentives for those who may actually act in ways to prevent release of the substance.[215] In addition, by requiring PRPs to cover government remediation costs, CERCLA risks government overcharges for prevention when at least some of the PRPs may more efficiently prevent environmental harm themselves.[216] Finally, critics have argued that the taxation provisions (now lapsed) provided insufficient incentives to prevent hazardous substance release because they were imposed on parties too far upstream in the distribution chain to have any meaningful downstream effect on hazardous substance release.[217]

Perhaps most importantly, CERCLA has been plagued with operational difficulties and funding challenges. Ultimately, CERCLA may provide a good example of how the second of the four factors considered previously – the (in)ability of private actors to pay for the harm caused[218] – can overwhelm the calculus and render ineffective an *ex post* liability scheme. Cleanup of hazardous waste sites has proven incredibly complex and costly. According to the Government Accountability Office, it takes the EPA an average of nineteen years to clean up a site designated on the National Priority List ("NPL").[219] More than half of the sites placed on the NPL in 1983 remain on this list.[220] Lack of funding has also led to delays in cleanup. Congressional appropriations have declined since 2003.[221] A September 2017 report from the EPA's inspector general suggested that over past years, the program has been plagued by understaffing, technical problems, a lack of data, and foot-dragging by companies deemed responsible for contamination.[222] The pace of site cleanup has similarly declined. From 1997 to 2000, the EPA averaged eighty-seven completed cleanups per year; by 2014, this number had dropped to just eight.[223]

Given CERCLA's funding challenges and increasing ineffectiveness, RCRA

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214 *See* Epstein, *supra* note 173, at 25-28.

215 *Id.* at 26-27.

216 *Id.* at 29.

217 *Id.* at 33.

218 *See supra* text accompanying note 186.

219 Ledyard King, *President Trump's Budget Would Cut Superfund Toxic Cleanup Program by 30%*, USA TODAY (Apr. 7, 2017), https://www.usatoday.com/story/news/politics/2017/04/07/president-trumps-budget-would-cut-superfund-toxic-cleanup-program-30/100168436/.

220 *Id.*

221 BEINS & LESTER, *supra* note 212, at 10, 72.

222 Joe Wertz, *EPA Vows to Speed Cleanup of Toxic Superfund Sites Despite Funding Drop*, NAT'L PUB. RADIO (Oct. 11, 2017), https://www.npr.org/2017/10/11/554564288/epa-vows-to-speed-cleanup-of-toxic-superfund-sites-despite-funding-drop.

223 BEINS & LESTER, *supra* note 212, at 12.

remains a key component in hazardous substance regulation. The statute has been described as a "monster" and a "bizarre jungle of rules and exceptions."[224] This article will focus only on the permitting and identification requirements for those who handle hazardous waste as most relevant to this discussion. RCRA lays out different requirements for the generation, transportation, recycling, treatment, storage, and disposal of hazardous waste.[225] Generators of hazardous waste are classified by size and must generally register with the EPA to receive an identification number.[226] Very small generators are subject to fewer requirements, but both small and large generators must satisfy numerous requirements including quantity limitations, accumulation time limits, tracking manifest requirements, and more.[227] Transporters must also receive an identification number and comply with RCRA's waste tracking manifest system, among other requirements.[228] Finally, so called Treatment, Disposal, and Storage Facilities ("TSDFs") are more stringently regulated because they present a higher risk.[229] TSDFs must obtain a RCRA permit that "establishes the administrative and technical conditions under which waste at the facility must be managed."[230] RCRA permits stipulate a wide array of requirements on the TSDF including the development of emergency plans, a requirement for insurance, training requirements in the handling of hazardous waste, and monitoring and compliance requirements.[231]

There are two key observations from these regulations that are noteworthy. First, RCRA gives the EPA broad authority to regulate the complete life cycle of activities associated with hazardous waste. Second, the EPA's chosen methodology to exercise this statutory authority has been to ratchet up regulatory requirements based on risk. Very small generators are perceived as low risk, and escape many of the regulations.[232] Likewise, TSDFs are perceived as high risk and are therefore subject to stringent permitting requirements.[233]

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224 Caroline N. Broun & James T. O'Reilly, *Introduction to RCRA Practice: Hazardous Waste Regulation Overview – Introduction*, 1 RCRA AND SUPERFUND: A PRACTICE GUIDE, 3D § 2:1 (2017).

225 *Learn the Basics of Hazardous Waste*, *supra* note 201.

226 *Hazardous Waste Generator Regulatory Summary*, ENVT'L. PROT. AGENCY, https://www.epa.gov/hwgenerators/hazardous-waste-generator-regulatory-summary (last updated Aug. 9, 2017).

227 *Id.*

228 *Hazardous Waste Transportation*, ENVT'L. PROT. AGENCY, https://www.epa.gov/hw/hazardous-waste-transportation#requirements (last updated Apr. 12, 2017).

229 *Learn the Basics of Hazardous Waste, supra* note 201.

230 *What Is a Hazardous Waste Permit?*, ENVT'L. PROT. AGENCY, https://www.epa.gov/hwpermitting/what-hazardous-waste-permit (last updated June 20, 2017).

231 *Id.*

232 *Hazardous Waste Generator Regulatory Summary*, *supra* note 226.

233 *See, What Is a Hazardous Waste Permit?*, *supra* note 230.

V. PROPOSAL FOR A WAY FORWARD

Armed with this panoply of environmental regulatory history and doctrinal theory, we are finally ready to turn toward a set of recommendations for how best to regulate microorganisms moving forward. It is wise to start with the four Shavell factors identified earlier, as these will help guide the balance between *ex ante* regulation and *ex post* liability. First, almost certainly for microorganisms, as with most emerging technologies, private actors who work with the technology will have more information about risks involved than the government. This should give us pause in suggesting heavy *ex ante* regulation, as it would likely lead to unfavorable outcomes. As we have seen, even when given broad discretion to regulate emerging technology, agencies have repeatedly taken approaches that lead to under- or over-regulation. At the same time, private actors may not have sufficient incentives to develop health and safety data. Imposing a mandate to develop this data, similar to FIFRA, may address this concern.

With regard to private parties' ability to pay for harm caused, the lessons from CERCLA are too difficult to ignore. While microorganisms may not create the same complexities and expense in clean-up activities as hazardous waste, the issue is that their risk profiles when released into the environment in large quantities are fundamentally not well understood. With billions or trillions of microorganisms released into the environment, we cannot completely discount the possible need for costly and complex clean-up efforts. This could be compounded due to the fact that the microbes are alive. Compared to hazardous chemicals, living microbes can multiply in quantity after release or affect other species' behavior causing unforeseen downstream effects. While Superfund remained solvent when taxes were in place, Congressional whims to change the tax code caution against relying too heavily on *ex post* liability alone to solve our problem.

With respect to whether parties fear liability from suit, as discussed, removing requirements for fault makes the most sense doctrinally with respect to microorganisms. This will lower barriers for bringing a liability suit against those who have caused harm. In addition, we should consider holding fewer parties liable, as criticisms of CERCLA have suggested, to provide better incentives for parties that must ultimately control their risky behavior. Finally, the costs incurred in a private liability scheme will certainly be lower than *ex ante* regulation, especially for those environmental releases that pose little to no risk. However, we might consider establishing a threshold for the release of large quantities of microorganisms over which the government establishes some regulatory control to help keep litigation costs down.

These general observations can help guide the proper statutory framework. What follows is not a piece of comprehensive legislation. Rather, it is a set of general suggestions that may form the basis of new regulations for microorganisms and could potentially apply to other emerging technologies as

well. Starting with new *ex ante* regulations, while not strictly required, it might work best to create a new statute governing microorganism use rather than shoring up or patching the set of statutes that cover microorganisms today. Microorganisms are sufficiently distinct from other types of toxic substances and pesticides to warrant separate treatment. This would also allow for a clean break from the limitations of those other statutes. This new legislation should also define "microorganism" broadly to extend coverage to all types.[234] A priori exclusions of whole categories of microorganisms makes little sense, especially if *ex ante* schemes are minimal.

The regulations should establish two related but independent systems. First, they should create a comprehensive registration and tracking system that will track private actors and the microorganisms they handle throughout the supply chain. This should cover researchers in the lab and include manufacturers, distributors, transporters, and ultimately those who release the microorganisms into the environment. In addition to tracking private actors, the system should track the microorganisms themselves as they change hands throughout the supply chain. The primary goals of the registration and tracking system are twofold: (1) to identify all actors who handle microorganisms throughout the supply chain from creation to release, (2) to gather enough additional data about the specific actors and their uses of microorganisms to establish risk profiles. Once this system is in place it can provide an important third benefit. It would provide a hook for regulators to attach additional regulations and requirements as needed going forward during registration or re-registration at any stage of the supply chain. As the technology matures, this *ex ante* regulatory structure can evolve with it. In the beginning, the registration and tracking system should be as thin as possible while satisfying the above two goals. This will help guard against a heavy-handed system that could stifle innovation and lead to the numerous problems discussed, *supra*, with *ex ante* regulation and emerging technology. As time moves on, however, one could imagine attaching a risk-based tax to encourage more responsible behavior or to help internalize risks that are not properly internalized through *ex post* liability schemes. Alternatively, regulators could consider attaching additional RCRA-like handling, storage, or training requirements for specific types of microorganisms based on risk and maturity of the technology. In short, information gathering is key. Once the full set of actors and risk profiles are known, regulators can add additional requirements based on this data when the need arises.

Related to the second goal of establishing appropriate risk profiles along the supply chain, *ex ante* regulations should require private actors to gather and publish health and safety data. These actors can gather this data much more

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234 The current regulatory definition defined in TSCA seems reasonable, but a better definition may exist. "Microorganism means an organism classified, using the 5–kingdom classification system of Whittacker, in the kingdoms Monera (or Procaryotae), Protista, Fungi, and the Chlorophyta and the Rhodophyta of the Plantae, and a virus or virus-like particle." 40 C.F.R § 725.3.

efficiently than the government, and the mandate to gather test data and publish it will eliminate any concern that private parties will not have sufficient incentives to understand their risks. Two aspects of the health and safety data requirements are worth noting. First, regulations should require publication of data before microorganisms are placed on the market or released into the environment above certain threshold quantities. In this regard, the testing requirements more closely mirror the "no data, no market" provisions of REACH, the European framework governing toxic substance control.[235] REACH requires a Chemical Safety Report before a chemical is placed on the market above threshold amounts.[236] Absent that data, REACH restricts or prohibits release of the chemical on the market.[237] Similar requirements should be utilized here. Second, regulations should require publication of health and safety data centrally so that it is available to the government and the public at large.[238] This will allow the government to better assess risk profiles for potential future regulations as the technology matures. But perhaps more importantly, it will enable those who work with the technology throughout the supply chain to pool their knowledge.

Generally, assessing risk of emerging technologies presents unique challenges. Historically, risk assessments for many types of GMOs, for example, have used comparators[239] to establish risk baselines.[240] However, as the synthetic biology techniques take GMOs farther afield from their non-GMO cousins, the use of comparators becomes harder.[241] Likewise, when microorganisms deviate from their naturally occurring states within ecosystems, such as when *Wolbachia* is used to affect entire populations of mosquitos, or when "multiple organisms [are] used in complex microbial communities," the use of comparators becomes impossible.[242] In such situations, some have suggested peer review and public participation in the risk assessment process.[243] With regard to the health and safety data discussed here, centralized publication of data will encourage information sharing and ultimately lead to more informed decision-making by actors throughout the supply chain.

Turning to the *ex post* liability provisions, we should hold anyone who releases microorganisms to the environment strictly liable for damages they cause to natural resources (including public resources) or others. Private citizens

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235 *See* John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 744 (2008).

236 *Id.*

237 *Id.*

238 This too resembles REACH. *See id.* at 750-51.

239 A non-GM organism that resembles the GMO except for the changed gene. NAT'L. ACAD. OF SCIENCES, *supra* note 149, at 7.

240 *Id.*

241 *Id.*

242 *Id.*

243 *Id.* at 12-13.

in the case of personal injury or the government in the case of public injury may bring suit. To guard against actors who irresponsibly incur risk over and above their assets, the government may monitor registration permits and, armed with health and safety data, deny permits to those whose assets do not cover the risk they wish to take on.[244] The limited set of responsible parties discussed here differs significantly from CERCLA, and would necessarily increase liability further down the supply chain. This could effectively increase liability for unsophisticated users of microorganisms downstream and limit liability for sophisticated manufacturers and distributors (though they too would be strictly liable for any accidental release to the environment). However, armed with publicly available health and safety data developed by upstream sophisticated actors, and prohibited from incurring risk through the registration process beyond their means, these actors would be incentivized to act responsibly. They also likely understand the risk associated with their activity better than the government, and thus *ex post* liability will likely lead to better outcomes than any form of *ex ante* regulation governing their behavior. Presumably these downstream actors could also contract with upstream parties to charge acceptance fees (or simply bargain for a lower purchase price) and distribute liability costs up the supply chain.[245]

VI. CONCLUSION

The emerging field of microorganisms holds great promise. Yet it presents unique challenges that require us to rethink current regulatory frameworks to achieve better outcomes. Critically assessing existing environmental statutes such as FIFRA, TSCA, RCRA, and CERCLA, and looking to doctrinal theories of tort law as a more efficient way of managing emerging technology risk, has led to this proposal for a new statutory scheme. The scheme borrows ideas from numerous sources and calls for a combination of *ex ante* regulation combined with *ex post* strict liability. Designed properly, these two mechanisms can strengthen each other, and more efficiently manage the emerging risks of microorganisms.

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[244] See Epstein, *supra* note 173, at 28-29 for a similar suggestion proposed in the context of CERCLA.

[245] See *id.* at 28 for a similar suggestion proposed in the context of CERCLA.