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BIOREMEDIATION: BREAKING DOWN THE REGULATIONS OF GENETICALLY MODIFIED MICROORGANISMS

*by: Lora Naismith**

Abstract

Environmental bioremediation is the use of biological activity to reduce the concentration or toxicity of a pollutant. A rapidly increasing population leads to a consequential increase in industrial waste and pollution, and innovators are researching numerous techniques to degrade these pollutants and prevent their spread into the environment. These techniques are expensive and often result in secondary pollutants, which limits their widespread application. Bioremediation, however, presents a cost-friendly and more efficient way to degrade pollutants with little or no secondary pollutants. This Article explores how scientists can use genetically modified microorganisms ("GMMs") to target specific hazardous wastes that are otherwise not degradable. Current U.S. laws and regulations only regulate GMMs on a case-by-case basis. With the rapidly advancing biotechnology sector, GMMs can provide cleaner, safer, and faster methods for cleaning up pollutants. However, as with all new sciences, GMMs pose unique risks when released directly into the environment. Regulations on the field release of GMMs are highly restrictive and hinder scientific research. This Article describes bioremediation and its potential risks; sets forth the current legal framework; and analyzes how policymakers can ensure the safe experimentation and eventual widespread use of GMMs in the environment.

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I. INTRODUCTION

As the human population continues to rise, so does energy consumption, carbon dioxide emissions, and pollution.[1] In the United States, almost 80% of our energy comes from fossil fuels.[2] The fossil fuel industry is well known for having many detrimental impacts on both human health and the environment; further, this industry is increasing drilling, fracking, and strip-mining operations to meet the increased energy demand.[3] Drilling and strip-mining not only take away large amounts of land but also create various forms of pollution such as oil spills or acid run-off.[4] Additionally, these extraction techniques produce large volumes of wastewater containing heavy metals and other pollutants.[5] After extraction, energy providers burn the fossil fuels and continue to pollute the environment by releasing carbon dioxide, nitrogen oxide, carbon monoxide, and heavy metals into the air.[6] Waste that is not released into the air is stored in landfills or underground wells, where it can potentially leak into waterways or aquifers.[7]

The health effects of these pollutants include increased cancer rates, birth defects, asthma and other respiratory illnesses, and according to some studies, autism, and a lower IQ.[8] These hazardous effects went largely unnoticed by lawmakers until the Love Canal disaster in the late 1970s, when a chemical company used a failed canal project in Niagara Falls, New York as an industrial waste dumpsite.[9] In 1953, the chemical company purchased Love Canal, covered the land, and sold it to the city.[10] A small town was then built on the land, and following a heavy rain in 1978, the buried industrial waste began leaching into the soil and basements.[11] Puddles of toxic chemicals filled the area;

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[1] *See* Lina Liu et al., *Mitigation of Environmental Pollution by Genetically Engineered Bacteria – Current Challenges and Future Perspectives*, 667 SCI. TOTAL ENV'T 444, 445 (2019), https://doi.org/10.1016/j.scitotenv.2019.02.390.

[2] *U.S. Energy Facts Explained*, U.S. ENERGY INFO. ADMIN., https://www.eia.gov/energyexplained/us-energy-facts/ [https://perma.cc/86PP-4WTA].

[3] Melissa Denchak, *Fossil Fuels: The Dirty Facts*, NAT. RES. DEF. COUNCIL (June 29, 2018), https://www.nrdc.org/stories/fossil-fuels-dirty-facts#sec-disadvantages [https://perma.cc/ZH56-YMW6].

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Health Impacts of Air Pollution*, ENV'T DEF. FUND, https://www.edf.org/health/health-impacts-air-pollution [https://perma.cc/3Q56-B5UW].

[9] Eckardt C. Beck, *The Love Canal Tragedy*, EPA J., Jan. 1979, at 17, 17, https://nepis.epa.gov/Exe/ZyPDF.cgi/93000CMP.PDF?Dockey=93000CMP.PDF [https://perma.cc/ZE44-YWXH].

[10] *Id.*

[11] *Id.*

trees and gardens died; and babies suffered from birth defects.[12] The potential for other waste sites just like the one at Love Canal led lawmakers to pass hazardous waste statutes and regulations for both the health of the public and the environment.[13] However, these fall short, especially in regard to developing technology.

Currently, hazardous waste producers must treat, store, or dispose of their waste.[14] Historically, producers either burned or buried their waste, but with more regulations, companies had to find other clean and effective waste-elimination methods.[15] This stimulated a move towards remediation, but current remediation procedures, such as incineration, are expensive and produce large amounts of hazardous waste byproducts.[16] Thus, hazardous waste producers turned to the cleaner and cheaper method of bioremediation.[17] Bioremediation presents an attractive treatment option with major benefits, including a wide scope of application, an undisturbed environment, and eliminating waste and toxicity.[18] Additionally, with the ever-advancing field of biotechnology, scientists can genetically modify microbial populations to target specific pollutants, withstand certain environments, and even die after completing the remediation.[19]

The current regulatory scheme governing the widespread release of genetically modified microorganisms ("GMMs") is vague and also rather restrictive.[20] The potential risks from releasing GMMs into the environment are not well known, but scientists speculate that the introduced genes could enter the environment and compromise "undesirable organisms."[21] Because of the unknown ecological effects, the field release of GMMs is heavily regulated, even for experimentation.[22] These restrictive regulations create a "research-commercialization gap," and without adequate field-testing and experimentation, the unknown effects will remain unknown, and scientists will be una-

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[12] *Id.*

[13] *Id.* at 18.

[14] *See id.*; *see also* Susan J. Timian & D. Michael Connolly, *The Regulation and Development of Bioremediation*, 7 RISK: HEALTH, SAFETY, & ENV'T 279, 280–81 (1996).

[15] R. BARRY KING ET AL., PRACTICAL ENVIRONMENTAL BIOREMEDIATION: THE FIELD GUIDE 2 (2d ed. 1998).

[16] Timian & Connolly, *supra* note 14, at 279.

[17] *Id.*

[18] KING ET AL., *supra* note 15, at 4.

[19] Gerd H. G. Moe-Behrens et al., *Preparing Synthetic Biology for the World*, FRONTIERS MICROBIOLOGY, Jan. 2013, at 1, 2, https://doi.org/10.3389/fmicb.2013.00005.

[20] Obidimma C. Ezezika & Peter A. Singer, *Genetically Engineered Oil-Eating Microbes for Bioremediation: Prospects and Regulatory Challenges*, 32 TECH. SOC'Y 331, 331–32 (2010), https://doi.org/10.1016/j.techsoc.2010.10.010.

[21] Mallavarapu Megharaj et al., *Bioremediation Approaches for Organic Pollutants: A Critical Perspective*, 37 ENV'T INT'L 1362, 1367 (2011), https://doi.org/10.1016/j.envint.2011.06.003.

[22] Ezezika & Singer, *supra* note 20, at 332.

ble to market their GMMs for bioremediation.[23] When developing a regulatory system, a government generally wants to ensure that science and technology "are safe for people and the environment, deliver the expected benefits, and are developed and used responsibly following high ethical standards."[24] A key decision-making factor in designing regulations is the risk assessment, which attempts to balance the potential benefits that come from using this developing technology with the potential harms, such as cost and environmental harm.[25]

To further develop GMMs for bioremediation, lawmakers must balance regulations that allow the bioremediation industry's continued innovation while also protecting human health and the environment. This Article first reviews laws that regulate waste management and the limitations of their current technology requirements. Part III explains the importance of bioremediation, how it works, and its current and potential risks. Part IV explains current GMM regulations and then recommends new ways to regulate GMMs based on similarities to existing statutes and possible biological requirements.

II. MANAGEMENT OF HAZARDOUS WASTE

A. *History of Waste Management*

Waste management practices are constantly adapting to match changes in production techniques and other advancing technologies.[26] In 1965, Congress passed the Solid Waste Disposal Act in response to a concerning rise in municipal waste.[27] This Act funded government research programs, which revealed numerous problems associated with high volumes of municipal waste and an increasing amount of hazardous industrial waste.[28] Due to the rapid expansion of the petrochemical industry, the volume and toxicity of industrial waste had increased by nearly 500% since the 1940s.[29] This led Congress to pass the Resource Conservation and Recovery Act of 1976 ("RCRA").[30] Prior to RCRA, however, waste producers usually dumped their waste in landfills and then left it alone, with no concern for its poten-

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[23] *Id.*

[24] DIV. ON EARTH & LIFE STUD., THE NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES 150 (2016), https://doi.org/10.17226/23405.

[25] *Id.*

[26] ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 346 (Rachel E. Barkow et al. eds., 8th ed. 2018).

[27] *See generally* Solid Waste Disposal Act, Pub. L. No. 89-272, 79 Stat. 997 (1965).

[28] *See* PERCIVAL ET AL., *supra* note 26, at 347.

[29] *Id.*

[30] *Id.*; *see generally* Resource Conservation and Recovery Act of 1976, Pub. L. No. 94-580, 90 Stat. 2795 (codified as amended in scattered sections of 42 U.S.C. §§ 6901–6992k).

tial long-term effects.[31] Many producers erroneously believed that the ground acted as a sponge, "absorbing without consequences any chemical compounds poured into it."[32] This mindset changed with the Love Canal disaster, after which Congress passed the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA").[33]

B. *Statutory Requirements for Waste Management*

Both RCRA and CERCLA sought to establish liability for mishandling hazardous wastes. RCRA established a "cradle-to-grave" liability scheme that holds responsible parties liable for clean-up costs dating from the waste's production through its disposal.[34] On the other hand, CERCLA holds parties responsible for clean-up costs if the party mishandles waste that causes some damage to public health or the environment.[35] A significant difference between these two statutes are the "bases for control," or what each statute aims to fix. There are three different bases for control: health, technology, and balancing.[36] A health-based statute uses medical studies to set adequate standards that protect and ensure the public health.[37] Strictly health-based statutes do not consider other issues such as whether meeting those standards is technologically feasible.[38] Contrarily, technology-based statutes structure regulatory standards on what is technologically feasible instead of addressing health concerns.[39] Agencies also determine whether the industry can bear the cost of implementing the technology.[40] Balancing-based statutes weigh regulatory benefits with the costs and potential risks of not regulating.[41]

RCRA's original goal was health-based, and Congress wanted to "promote the protection of health and the environment" by making land disposal safer and moving away from using landfills.[42] However, industries continued using landfills as a cheap method for waste dispo-

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[31] PERCIVAL ET AL., *supra* note 26, at 347.

[32] *Id.*

[33] Benjamin Raker, Note, *Reading Remedially: What Does* King v. Burwell *Teach Us About Modern Statutory Interpretation, and Can It Help Solve the Problems of CERCLA § 113(h)?*, 70 VAND. L. REV. 1143, 1157 (2017); *see generally* Comprehensive Environmental Response, Compensation, and Liability Act of 1980, Pub. L. No. 96-510, 94 Stat. 2767 (codified as amended at 42 U.S.C. §§ 9601–9675).

[34] *Resource Conservation and Recovery Act (RCRA) and Federal Facilities*, ENV'T PROT. AGENCY, https://www.epa.gov/enforcement/resource-conservation-and-recovery-act-rcra-and-federal-facilities [https://perma.cc/MS8Y-YGEG].

[35] Timian & Connolly, *supra* note 14, at 281–83.

[36] PERCIVAL ET AL., *supra* note 26, at 158–59.

[37] *Id.* at 158.

[38] *Id.* at 160.

[39] *Id.* at 159.

[40] *Id.* at 160.

[41] *Id.* at 159.

[42] Resource Conservation and Recovery Act of 1976, Pub. L. No. 94-580, § 1003, 90 Stat. 2795, 2798 (codified at 42 U.S.C. § 6902(a)).

sal.[43] Consequently, Congress amended RCRA to force the development of alternative disposal technologies.[44] The 1984 Amendments banned land disposal[45] and also shifted RCRA from primarily health-based to technology-based standards.[46] These technology standards require that waste be disposed of using the "best demonstrated available technology."[47] The Environmental Protection Agency ("EPA") sets the technology requirements, which limit companies to using established technologies to dispose of hazardous waste.[48]

CERCLA operates under a balancing standard that focuses mostly on human health with a "cost-effectiveness constraint."[49] The main goals of CERCLA are "to clean up hazardous waste sites promptly and effectively" and to make hazardous waste creators "bear the costs and responsibility for remedying the harmful conditions they created."[50] Additionally, CERCLA has a technology standard similar to RCRA's, but it has an additional provision that allows for an "[a]lternative or innovative treatment technology research and demonstration program."[51] This program was an amendment incentivizing a move towards remediation techniques that "permanently and significantly reduce[] the volume, toxicity or mobility of the hazardous substances, pollutants, and contaminants."[52] CERCLA's health-based focus on permanently remediating contaminated sites promotes using and improving remediation technologies.

In debating the 1984 RCRA Amendments, U.S. Senator John Chafee said that "as long as cheap land disposal options are available," there will not be "a viable market to support the development and expansion of new, safer treatment and disposal technologies."[53] Chafee's idea is bolstered by the fact that industries commonly overestimate the cost of compliance with a new environmental regulation in an attempt to dissuade regulators from adopting the new regulation.[54] Overestimating costs stunts technological innovation, even

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[43] *See* PERCIVAL ET AL., *supra* note 26, at 358.

[44] *Id.*

[45] *Id.*; *see* 42 U.S.C. § 6924(c)–(m).

[46] PERCIVAL ET AL., *supra* note 26, at 366.

[47] Timian & Connolly, *supra* note 14, at 283; *see also* 42 U.S.C. § 6924(o).

[48] *See RCRA: Browse Topics*, ENV'T PROT. AGENCY, https://rcrapublic.epa.gov/rcraonline/topics.xhtml [https://perma.cc/X6XT-3KHE] (listing the different technological requirements for various types of waste under the "best demonstrated available technology" standard).

[49] PERCIVAL ET AL., *supra* note 26, at 353.

[50] Blake A. Watson, *Liberal Construction of CERCLA Under the Remedial Purpose Canon: Have the Lower Courts Taken a Good Thing Too Far?*, 20 HARV. ENV'T L. REV. 199, 202–03 (1996) (quoting United States v. Reilly Tar & Chem. Corp., 546 F. Supp. 1100, 1112 (D. Minn. 1982)).

[51] 42 U.S.C. § 9660(b).

[52] *Id.* § 9621(b)(1).

[53] 130 Cong. Rec. 30,697 (1984) (Senator John Chafee debating the 1984 Amendments to the RCRA).

[54] PERCIVAL ET AL., *supra* note 26, at 169.

though innovation could potentially lower compliance costs and improve the environment.[55] Despite the fact that both RCRA and CERCLA have provisions spurring technological innovation, industries continue using the cheapest or most readily available waste management methods.[56]

C. *Waste Management Methods*

Under RCRA, facilities are responsible for storing, treating, and disposing of hazardous waste.[57] Prior to treatment or disposal, facilities can temporarily store hazardous wastes in containers, such as steel drums for transportation, stationary tanks, or containment buildings.[58] Each storage facility must comply with regulations to ensure proper design and operation of storage units.[59]

Treatment is the most preferred method because it can minimize or eliminate the toxicity of the hazardous waste.[60] Treating a hazardous waste essentially alters the waste's "character or composition."[61] Common treatment methods include incineration and many remediation types.[62] Incineration uses fire to burn and destroy waste,[63] while remediation removes its toxic elements.[64] Current remediation methods include chemical treatment, adsorption, coagulation, oxidation, and bioremediation.[65] Chemical treatment separates and neutralizes heavy metals found in many hazardous wastes, most commonly wastewater from burning fossil fuels.[66] Adsorption uses certain solid materials to adsorb organic compounds, heavy metals, and other hydrocarbons out of water, whereas coagulation causes the pollutants to clump together and sink.[67] Oxidation introduces various chemicals in a specific sequence to separate the pollutants.[68] Some treatment methods, such as boilers or industrial furnaces, can isolate and reuse

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[55] *Id.*

[56] *See* Rick LeBlanc, *Waste Treatment and Disposal Methods*, THE BALANCE: SMALL BUS., https://www.thebalancesmb.com/waste-treatment-and-disposal-methods-2878113 (May 9, 2019) [https://perma.cc/V9NJ-3J7V].

[57] *Hazardous Waste Management Facilities and Units*, ENV'T PROT. AGENCY, https://www.epa.gov/hwpermitting/hazardous-waste-management-facilities-and-units#unit [https://perma.cc/2XPC-22B5]; *see* 42 U.S.C. § 6924.

[58] *Hazardous Waste Management Facilities and Units*, *supra* note 57.

[59] *Id.*

[60] KING ET AL., *supra* note 15, at 3.

[61] *Hazardous Waste Management Facilities and Units*, *supra* note 57.

[62] Janick F. Artiola, *Industrial and Municipal Solid Waste Treatment and Disposal*, *in* ENVIRONMENTAL AND POLLUTION SCIENCE 415, 419–23 (Pepper et al. eds., 2d ed. 2006).

[63] *Id.* at 422–23.

[64] *Id.* at 419.

[65] *See id.* at 419–21.

[66] *Id.* at 419.

[67] *See id.* at 419–20.

[68] *Id.* at 420–21.

parts of the waste in manufacturing or simply burn the waste for energy. However, facilities still must dispose of the separated waste.

The most common disposal method today remains landfills, which the EPA defines as "excavated or engineered sites where non-liquid hazardous waste is deposited for final disposal and covered."[69] Various landfill types handle different waste types. For example, a hazardous waste landfill must have a double liner and leachate[70] collection and removal systems.[71] Additionally, the EPA highly regulates landfills for leaks, groundwater contamination, or landfill gas.[72] Another disposal method specifically for liquid wastes is deep-well injection.[73] This method pumps waste into a confined area between 2,000 and 7,000 feet underground.[74] Deep-well injection generally disposes of wastewaters with high levels of toxic chemicals, including pesticides, heavy metals, or radioactive waste.[75]

However, these disposal methods are not fool-proof because hazardous wastes can escape unintentionally, either from the treatment method failing or an accidental release like an oil spill.[76] Currently, remediating unintentionally released hazardous waste involves treating the waste with chemical or physical processes, containing the waste to prevent spread, or removing the waste to a closed environment.[77] Similar to RCRA-managed wastes, treatment is the most preferred method as it can eliminate the hazardous waste's toxicity.[78] The most common treatment method for contaminated groundwater is the "pump-and-treat" method, where an extraction well pumps out the contaminated water, which is then treated.[79] This method also remediates contaminated soil by introducing water to the contaminated area, treating the mixture of soil and water, and replacing the soil after extracting the contaminants.[80] This method could take decades depending on the amount of contaminant and it still fails to completely remove all contaminants.[81] When treatment is not feasible,

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[69] *Hazardous Waste Management Facilities and Units*, *supra* note 57.

[70] Leachate is made when water moves through hazardous waste and dissolves components of the waste. Artiola, *supra* note 62, at 425–26.

[71] *Hazardous Waste Management Facilities and Units*, *supra* note 57.

[72] *Id.*; *see also* OFF. OF RSCH. & DEV., EPA, POST-CLOSURE PERFORMANCE OF LINER SYSTEMS AT RCRA SUBTITLE C LANDFILLS 7 (2017).

[73] Artiola, *supra* note 62, at 421–22.

[74] *Id.* at 421.

[75] *Id.*

[76] Ian L. Pepper et al., *The Extent of Global Pollution*, *in* ENVIRONMENTAL AND POLLUTION SCIENCE 3, 5 (Pepper et al. eds., 2d ed. 2006).

[77] Mark L. Brusseau, *Soil and Groundwater Remediation*, *in* ENVIRONMENTAL AND POLLUTION SCIENCE 312, 318, 325 (Pepper et al. eds., 2d ed. 2006).

[78] *Id.*

[79] *Id.* at 321.

[80] *Id.*

[81] Carol Litchfield, *Thirty Years and Counting: Bioremediation in Its Prime?*, 55 BIOSCI. 273, 273 (2005).

facilities use containment and removal techniques.[82] Common containment methods essentially quarantine waste to a specific area using physical barriers or solidifying the waste.[83] A common removal technique involves excavating the contaminated area, which personnel then treat or dispose of.[84] But excavation can expose workers to the hazardous material and is usually only effective and cost-efficient for small and shallow areas.[85]

Current waste management methods have severe limitations and often themselves produce "secondary environmental pollutants" that then require containment or disposal.[86] For example, incineration produces fly ash and various air pollutants,[87] and chemical treatment produces sludge high in heavy metals and other volatile compounds.[88] Additionally, even when hazardous waste is treated, the hazard is merely transferred from one media to the next.[89] For instance, incineration removes toxins from the solid waste by burning it, but burning waste releases gases into the air.[90] Some methods further disrupt the environment because they require removing large quantities of polluted material.[91] Several chemical methods also use toxic or foreign chemicals, which require additional monitoring, and these methods may or may not effectively clean the pollutant.[92] Many methods also have high operating costs, use expensive equipment, and require large quantities of chemicals and skilled labor.[93] High costs encourage hazardous waste generators to contract hazardous waste management companies for remediation, allowing the generators to "focus their efforts on their primary business."[94] This outsourcing also increases demand for "improved waste disposal and cleanup technologies."[95] Developing these technologies shows that bioremediation can provide a more cost-efficient method that results in little or no hazardous by-

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[82] Brusseau, *supra* note 77, at 318.

[83] *Id.* at 319–20.

[84] *Id.* at 321.

[85] *Id.*

[86] Arun Kumar Dangi et al., *Bioremediation Through Microbes: Systems Biology and Metabolic Engineering Approach*, 39 CRITICAL REVS. BIOTECH. 79, 80 (2019), https://doi.org/10.1080/07388551.2018.1500997; *see also* Pardeep Singh et al., *Current and Emerging Trends in Bioremediation of Petrochemical Waste: A Review*, 47 CRITICAL REVS. ENV'T SCI. & TECH. 155, 161 (2017), https://doi.org/10.1080/10643389.2017.1318616.

[87] Artiola, *supra* note 62, at 422.

[88] *See* Grégorio Crini & Eric Lichtfouse, *Advantages and Disadvantages of Techniques Used for Wastewater Treatment*, 17 ENV'T CHEM. LETTERS 145, 148 (2019), https://doi.org/10.1007/s10311-018-0785-9.

[89] Artiola, *supra* note 62, at 419.

[90] *Id.* at 422.

[91] *See* Brusseau, *supra* note 77, at 321; JAMES G. SPEIGHT, REACTION MECHANISMS IN ENVIRONMENTAL ENGINEERING: ANALYSIS AND PREDICTION 287 (2018).

[92] *See* Crini & Lichtfouse, *supra* note 88, at 148.

[93] *See id.*

[94] KING ET AL., *supra* note 15, at 3.

[95] *See* Timian & Connolly, *supra* note 14, at 290.

products.[96] Even so, commercializing bioremediation is not without its difficulties.

III. Bioremediation

A. *History and Current Uses*

Bioremediation broadly means the "[r]emediation of polluted sites using microbial process."[97] Bioremediation originated with the ancient Romans' use of microorganisms for wastewater purification.[98] While the Romans may not have known the exact process, they did design their sewage system to collect in vats, where they believed the wastewater went through "self-purification."[99] This is now called self-remediation, or natural attenuation, which occurs when native microbial species degrade pollutants or waste in the natural environment.[100] Modern bioremediation began with a 1975 report detailing how adding nutrients to soil that was contaminated by an oil spill increased the amount of bacteria that degrade petroleum waste, which consequently increased the waste-removal rate.[101] Researchers further developed this process to provide a cleaner and more efficient way to treat gas station and refinery spills.[102] Bioremediation's success in treating these spills led researchers to explore more applications, and their studies found that certain microbes can degrade chlorinated hydrocarbons, heavy metals, and other pollutants.[103] And with the biotechnology field's advances in genetically modifying organisms, scientists are researching and creating bacteria with augmented pollutant-degradation capabilities.[104] The first genetically modified microbe originated in 1971, when a scientist combined the genetic material from four different bacterial strains to create a bacteria that was capable of breaking down crude oil 10–100 times faster than non-genetically modified microbes.[105]

Bioremediation techniques are usually split into two classifications: *ex situ* or *in situ*.[106] *Ex situ* bioremediation involves excavating the pollutant and then transporting it to a treatment facility.[107] Municipal

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[96] *Id.* at 279.

[97] Christopher Chibueze Azubuike et al., *Bioremediation Techniques–Classification Based on Site of Application: Principles, Advantages, Limitations and Prospects*, 32 World J. Microbiology & Biotech. 180, 180 (2016), https://doi.org/10.1007/s11274-016-2137-x.

[98] King et al., *supra* note 15, at 1.

[99] *Id.*

[100] Singh et al., *supra* note 86, at 156.

[101] Litchfield, *supra* note 81, at 273.

[102] *Id.*

[103] King et al., *supra* note 15, at 5.

[104] Liu et al., *supra* note 1, at 445.

[105] Ezezika & Singer, *supra* note 20, at 332.

[106] Megharaj et al., *supra* note 21, at 1366.

[107] *Id.*

wastewater plants commonly use *ex situ* bioremediation for activated sludge treatment.[108] This process introduces various microbes to the wastewater for aeration, agitation, and re-circulation until the waste is adequately degraded.[109] *Ex situ* bioremediation also treats groundwater and contaminated soil, which is seen in the "pump-and-treat" method described in the previous Part.[110] Because most *ex situ* techniques require excavation and transport and occur in a closed environment, the costs are significantly higher than those for *in situ* remediation.[111] However, *ex situ* bioremediation mitigates risks that stem from treating an open system.[112]

In situ techniques degrade the pollutant on site.[113] There are three types of *in situ* bioremediation: (1) bioattenuation; (2) biostimulation; and (3) bioaugmentation.[114] Bioattenuation, also called natural attenuation, refers to the natural degradation processes at the pollution site.[115] This process is contaminant-specific, and the degradation time varies drastically from site to site.[116] Biostimulation accelerates the natural processes by adding nutrients to the microbes.[117] This process requires extensive studies to maintain the ecological balance that the microbes need.[118] Bioaugmentation introduces additional microbes to degrade pollutants.[119] The introduced microbes convert toxic pollutants into non-hazardous compounds and will eventually reduce or even eliminate the pollutant from the contaminated area.[120]

In practice, *in situ* bioremediation generally treats organic pollutants.[121] The Exxon Valdez and BP Deepwater Horizon oil spills both resulted in successful *in situ* bioremediation cleanup efforts.[122] While biodegradation and other natural processes will remove most crude oil in low concentrations, the natural processes alone could take years to degrade the high concentration of crude oil after a spill.[123] The 1989

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[108] *See* Charles P. Gerba & Ian L. Pepper, *Municipal Wastewater Treatment*, *in* ENVIRONMENTAL AND POLLUTION SCIENCE 429, 435 (Pepper et al. eds., 2d ed. 2006).

[109] *Id.*

[110] *See supra* notes 79–81 and accompanying text.

[111] SPEIGHT, *supra* note 91, at 281–82.

[112] *Id.*

[113] Megharaj et al., *supra* note 21, at 1366.

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] *Id.*

[118] *Id.*

[119] EPA, GREEN REMEDIATION BEST MANAGEMENT PRACTICES: BIOREMEDIATION 1 (2010), https://semspub.epa.gov/work/HQ/147895.pdf [https://perma.cc/KM2G-MVBH].

[120] Liu et al., *supra* note 1, at 445.

[121] Brusseau, *supra* note 77, at 325.

[122] Ronald M. Atlas & Terry C. Hazen, *Oil Biodegradation and Bioremediation: A Tale of the Two Worst Spills in U.S. History*, 45 ENV'T SCI. & TECH. 6709, 6709 (2011), https://doi.org/10.1021/es2013227.

[123] *See id.*

Exxon Valdez oil spill occurred after a ship ran aground and spilled eleven million gallons of crude oil, which gathered on the water's surface.[124] After running laboratory tests, the government approved using a bioremediation technique to increase the amount of microbes that degrade crude oil.[125] By 1992, this technique significantly reduced the amount of oil on 98.7% of the affected shoreline.[126] While the oil in Exxon Valdez collected on the water's surface, the Deepwater Horizon oil spill released crude oil into the Gulf of Mexico at high pressures from various breaks around the drilling platform on the ocean floor.[127] The high pressure led to the spilled oil collecting in "clouds" surrounding the drilling platform.[128] Additionally, the native microbe population in the Gulf of Mexico was better adapted to degrading oil than the microbe population in the Exxon Valdez spill.[129] Due to the lower oil concentration and the better-adapted native population, no additional microbes or microbe-increasing techniques were necessary. So the Deepwater Horizon spill called for a type of monitored natural attenuation.[130] This technique succeeded, and roughly two weeks after the oil spill stopped, there was no observable oil on the water's surface and the oil concentration had decreased significantly.[131]

These successful uses spurred both private and government entities to fund innovation for bioremediation techniques. The U.S. National Institute of Environmental Health Sciences has a Superfund Research Program that supports research for developing new bioremediation technologies for hazardous wastes,[132] and the U.S. Department of Energy has also funded research under its Biological and Environmental Research program.[133] Additionally, international public institutes in India and China are funding bioremediation research.[134] With this funding, scientists are developing GMMs with many potential bioremediation uses.[135]

One potential use is degrading synthetic dyes.[136] Several industries, such as textiles, printing, and cosmetics use synthetic dye, and they

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[124] *Id.* at 6710.

[125] *Id.* at 6711.

[126] *Id.* at 6710–11.

[127] *Id.* at 6712.

[128] *Id.* at 6712–13.

[129] *Id.* at 6713–14.

[130] *See id.* at 6712–14.

[131] *Id.* at 6714.

[132] *See Superfund Research Program*, NAT'L INST. OF ENV'T HEALTH SCIS., https://www.niehs.nih.gov/research/supported/centers/srp/index.cfm (Mar. 3, 2021) [https://perma.cc/NPZ6-73C5].

[133] *See Funding Opportunities*, U.S. DEP'T OF ENERGY, https://science.osti.gov/ber/Funding-Opportunities [https://perma.cc/5B86-BEKD].

[134] *E.g.*, Wang Jianlong et al., *Bioaugmentation as a Tool to Enhance the Removal of Refractory Compound in Coke Plant Wastewater*, 38 PROCESS BIOCHEMISTRY 777, 777, 780 (2002); Liu et al., *supra* note 1, at 452; Megharaj et al., *supra* note 21, at 1362.

[135] Liu et al., *supra* note 1, at 445.

[136] *Id.* at 447.

discharge roughly 10% to 15% of the dye as wastewater.[137] Synthetic dyes, in addition to their byproducts, are highly toxic and potentially carcinogenic.[138] Current degradation practices, as described above, are unable to completely eliminate the dyes' toxicity, but engineered GMMs increase the efficiency of degrading dyes while producing less hazardous byproducts.[139] Another potential use is degrading heavy metals, which are released into the atmosphere when burning fossil fuels.[140] These metals adversely affect human health and the environment.[141] Aside from being costly, current practices for eliminating heavy metals produce large amounts of hazardous byproducts.[142] However, GMMs can reduce the amount of mercury, cadmium, and copper from the atmosphere.[143] Additionally, bioaugmentation successfully treated coke-plant wastewater in a Chinese experiment.[144] Coal is a primary energy source for China, and coke wastewater is a byproduct of coal burning.[145] This experiment showed that adding a specific microorganism resulted in a high degradation of a chemical byproduct that conventional methods had failed to degrade.[146] Thus, GMMs could provide an effective bioremediation method for coke wastewater.[147] Because current waste disposal practices create hazardous byproducts, a shift towards GMMs can both reduce those byproducts and also create cost-effective methods that incentivize companies to use bioremediation.

B. *Benefits of Bioremediation*

Bioremediation provides a more cost-effective replacement to current waste management techniques.[148] For example, bioremediation in the Exxon Valdez oil spill cleaned seventy-five miles of shoreline for less than what it would have cost for one day using traditional oil-spill cleaning methods.[149] Additionally, private companies are conducting experiments to outline bioremediation's actual cost-effectiveness.[150] Regenesis[151] conducted a two-year experiment on 400 square feet of

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[137] *Id.*

[138] *Id.*

[139] *Id.*

[140] *See id.* at 448.

[141] *Id.*

[142] *Id.*

[143] *Id.* at 448–49.

[144] Jianlong et al., *supra* note 134, at 777.

[145] *Id.*

[146] *Id.* at 780.

[147] *Id.*

[148] Speight, *supra* note 91, at 287.

[149] *Id.*

[150] *See In Situ Aerobic Bioremediation vs. AS/SVE Cost Comparison at UST Site*, Regenesis, https://regenesis.com/en/project/orc-vs-assve-cost-comparison-ust-site-covington/ [https://perma.cc/G4ES-AK7P].

[151] *Advancing Environmental Remediation Solutions Since 1994*, Regenesis, https://regenesis.com/en/who-we-are/ [https://perma.cc/EYB7-N3NV].

leaking underground storage tanks with both a bioremediation method and a non-bioremediation method.[152] The non-bioremediation method cost about $192,600, whereas the bioremediation method only cost $113,149, a difference of $79,451.[153] In addition to private companies, the U.S. government has used both *in situ* and *ex situ* bioremediation methods at Superfund sites.[154] Costs ranged from $2 to $300 per cubic yard, with most sites being around $40 per cubic yard.[155] Most sites met their remediation clean-up goals, while others significantly reduced contamination.[156] Bioremediation is generally more cost-effective because it requires less equipment and oversight than traditional remediation methods.[157]

In addition to being cost-effective, bioremediation is also better for the environment. As mentioned in Part II, traditional waste management methods involve the use of toxic chemicals for treatment, disturb the environment by excavating and removing polluted material, and produce secondary byproducts.[158] The government and private companies can use bioremediation instead of toxic chemicals at the polluted site, which further eliminates any need for excavation and removal.[159] Further, microbes use biological pathways that degrade and change the chemical compositions of pollutants—lessening their toxicity by producing non-hazardous byproducts such as carbon dioxide and water.[160] Overall, bioremediation provides a cleaner and more environmentally friendly way to treat hazardous wastes.

Further research and development of GMMs for bioremediation could potentially address pollutants that cannot currently be degraded.[161] For example, radioactive wastes are harder to treat and generally require storage until the waste is no longer radioactive.[162] This treatment method can take hundreds of years and relies on the waste's natural ability to degrade itself.[163] Modified, radiation-resistant bacteria can efficiently degrade radioactive waste, introducing a new waste management method for this specific type of waste.[164] Fi-

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[152] *In Situ Aerobic Bioremediation vs. AS/SVE Cost Comparison at UST Site*, *supra* note 150.

[153] *Id.*

[154] *See generally* EPA, USE OF BIOREMEDIATION AT SUPERFUND SITES (2001), https://www.epa.gov/sites/production/files/2015-08/documents/bioremediation_542r01019.pdf [https://perma.cc/F9U5-B3TV].

[155] *Id.* at 2.

[156] *Id.* at 17.

[157] SPEIGHT, *supra* note 91, at 287.

[158] *See supra* notes 86–92 and accompanying text.

[159] SPEIGHT, *supra* note 91, at 287.

[160] *See* Christopher Rensing et al., *Genetically Engineered Crops and Microbes*, *in* ENVIRONMENTAL AND POLLUTION SCIENCE 489, 496 (Pepper et al. eds., 2d ed. 2006).

[161] SPEIGHT, *supra* note 91, at 296.

[162] *See* U.S. NUCLEAR REGUL. COMM., RADIOACTIVE WASTE 2, 4 (2019), https://www.nrc.gov/docs/ML0501/ML050110277.pdf [https://perma.cc/2NBZ-BZU2].

[163] *See* SPEIGHT, *supra* note 91, at 354.

[164] Ezezika & Singer, *supra* note 20, at 332.

nally, researchers can modify bacteria to address new wastes emerging from developing industrial technologies, providing a cost-effective, environmentally friendly, and adaptable method for treating hazardous wastes.[165]

C. *Risks of Genetically Modified Microorganisms*

Despite many benefits, releasing GMMs into the environment poses risks that are currently speculative and difficult to measure.[166] Most risks arise from containment.[167] If GMMs spread beyond the treatment area, they could interact with other organisms, cause unknown mutations, and affect the ecology of the surrounding area.[168] The most unpredictable risk is the interaction of GMMs with other organisms in the environment.[169] For example, a GMM was developed to degrade Agent Orange, a toxic defoliant that the United States used during the Vietnam War.[170] The EPA was concerned that the inserted gene that allowed the GMMs to degrade Agent Orange could be transferred to nearby bacteria by natural gene-transfer processes.[171] While the main concern with unintentional gene transfer is the potentially adverse effects on human health and the environment, the exact effects are difficult to predict because the genetic information can compromise a variety of organisms and cause widely variable outcomes.[172] There are also ethical concerns because introducing foreign genes threatens the "integrity and the intrinsic value of the organisms involved."[173] Consequently, the EPA maintains that genetically modifying microorganisms constitutes a "high risk," regardless of application.[174]

Additionally, GMMs can take essential resources away from the native microbe populations.[175] GMMs could outcompete the native microbes and eventually spread into other habitats, becoming somewhat of an invasive species.[176] Invasive species have cost North America roughly $120 billion in damages and are the primary extinction risk for about half of the threatened or endangered species in the United States.[177] A directive from the European Union ("E.U.") similarly re-

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[165] *See* SPEIGHT, *supra* note 91, at 296.

[166] Moe-Behrens et al., *supra* note 19, at 1.

[167] *Id.*

[168] *Id.*

[169] *See* Ezezika & Singer, *supra* note 20, at 332.

[170] *Id.*

[171] *Id.*

[172] Paul Keese, *Risks from GMOs Due to Horizontal Gene Transfer*, 7 ENV'T BIOSAFETY RSCH. 123, 132 (2008), https://doi.org/10.1051/ebr:2008014.

[173] *Id.*

[174] Ezezika & Singer, *supra* note 20, at 332–33.

[175] Dangi et al., *supra* note 86, at 90.

[176] *Id.*

[177] Karrigan Bork, *Guest Species – What About the Nonnative Species We Like?*, CAL. WATERBLOG (May 28, 2018), https://californiawaterblog.com/2018/05/28/guest-species-what-about-the-nonnative-species-we-like/ [https://perma.cc/55DR-ZWW9].

flects concern with the unpredictable and potentially irreversible effects of releasing genetically modified organisms into the environment.[178] The directive stated, "Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States."[179]

When there is insufficient information to determine an unreasonable risk under current regulations, the EPA may completely ban production which, in the case of GMMs, is highly restrictive and detrimental to future GMM development.[180] While GMMs have so many positive potential effects, those effects will remain hidden until GMM regulations are less restrictive and permit further research and development.

IV. Regulating Genetically Modified Microorganisms

Currently, the only statute governing GMMs for bioremediation is the Toxic Substances Control Act ("TSCA"),[181] but it has many gaps, leaving risks unaddressed.[182] Because bioremediation with GMMs poses unique risks, developing a regulatory scheme that addresses these risks without hindering research and development is important for mitigating the potential harm of hazardous waste. Regulators should determine if they or private parties know more about the potential risks associated with GMMs.[183] Where private parties know more about the potential risks, regulations imposing liability function better than preventative regulations.[184] In these situations, agencies tend to either overestimate the risk and impose regulations that are overly strict, or they underestimate the risk and impose regulations that are too lenient.[185] Imposing liability regulations would be more effective because private parties are motivated to minimize the potential risks to avoid being financially responsible for any harm caused.[186] Conversely, if the regulator knows more about the potential risks, the agency is able to regulate with more accuracy, and preventative regulations are neither too strict nor lenient.[187] As GMMs are still being researched and developed, this Part first discusses ways to regulate

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[178] Council Directive 2001/18, 2001 O.J. (L 106) 1, 1 (EC).

[179] *Id.*

[180] 15 U.S.C. § 2605(a).

[181] *See id.* §§ 2601–2695d.

[182] Matthew McKerley, Comment, *It Takes Two to Tango: Regulating the Emerging Risks of Microorganisms*, 42 Environs Env't L. & Pol'y J. 1, 14 (2018).

[183] Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. Legal Stud. 357, 359 (1984).

[184] *Id.*

[185] *Id.*

[186] *Id.*

[187] *Id.*

research and experimental field releases. It then discusses both precautionary regulations and liability regulations to address the uncertain risks associated with GMMs.

A. *Toxic Substances Control Act*

The 1975 Asilomar Conference gathered scientists, lawyers, ethicists, and physicians to discuss the release of genetically modified organisms into the environment.[188] This Conference addressed concerns that genes introduced into other cells could alter harmless microbes into cancer-causing agents or human pathogens.[189] However, these concerns centered on the accidental release from a closed laboratory setting and not intentional environmental release.[190] After Asilomar, the Office of Science and Technology Policy issued the Coordinated Framework for Regulation of Biotechnology.[191] The Framework essentially said that current statutes sufficiently regulated biotechnology and it was unnecessary to legislate new statutes for technologies that were still in the research pipeline.[192] Under the Framework, the EPA, Food and Drug Administration, and Animal and Plant Health Inspection Service are responsible for regulating different aspects of biotechnology.[193]

The current applicable statute for using GMMs in environmental bioremediation is TSCA.[194] TSCA initially served a gap-filling purpose for chemical substances that were not regulated under another statutory program.[195] TSCA's legislative history reflects "growing concern about the risks that chemicals used in commerce posed to public health and the environment."[196]

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[188] 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 58 (Chris A. Wozniak & Alan McHughen eds., 2013).

[189] Paul Berg, *Asilomar 1975: DNA Modification Secured*, 455 NATURE 290, 290 (2008).

[190] *Id.*

[191] Wozniak et al., *supra* note 188, at 57–58. The Office of Science and Technology Policy is in the Executive Office of the President. *Office of Science and Technology Policy*, THE WHITE HOUSE, https://www.whitehouse.gov/ostp/ [https://perma.cc/L576-PBBJ].

[192] Wozniak et al., *supra* note 188, at 59.

[193] *Id.* For reference, the Animal and Plant Health Inspection Service is under the Department of Agriculture. ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.aphis.usda.gov/aphis/home [https://perma.cc/FDU9-R3VF].

[194] *See* Wozniak et al., *supra* note 188, at 76; *see generally* 15 U.S.C. §§ 2601–2695d.

[195] McKerley, *supra* note 182, at 9.

[196] David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and Its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL'Y 333, 340 (2010).

TSCA restricts the manufacturing of chemical substances that are not in TSCA's Chemical Substance Inventory.[197] A chemical substance is "any organic or inorganic substance of a particular molecular identity," which includes substances "occurring in whole or in part as a result of a chemical reaction or occurring in nature."[198] Since 1977, the EPA has interpreted this definition broadly to include "life forms which may be manufactured for commercial purposes."[199] As such, the statute encompasses intergeneric microorganisms, which TSCA regulations define as "a microorganism that is formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera."[200] Therefore, TSCA does not apply to GMMs created by introducing a lab-created gene.

TSCA requires "persons who manufacture, import, or process microorganisms for commercial purposes" to submit a notice called the Microbial Commercial Activity Notice ("MCAN") to the EPA.[201] The EPA reviews the MCAN to both identify and classify the microorganism into TSCA's Chemical Substance Inventory as well as determine if the GMM is likely to present an "unreasonable risk" to public health or the environment.[202] The MCAN requires: identifying the microorganism and its potential effects on human health and the environment; describing the microorganism's genetic modifications and stability, and the potential for its genetic material to transfer into the environment; and detailing the manufacturing process as well as containment and inactivation periods.[203]

However, TSCA can exempt GMMs from reporting an MCAN for research and development.[204] At the research and development stage, a GMM manufacturer must submit a TSCA Experimental Release Application ("TERA") sixty days before initiating the experiment.[205] The EPA then reviews the TERA to determine if the proposed activity presents an "unreasonable risk of injury to health or the environment."[206] If the EPA is unable to reach a conclusion, then it will deny the TERA.[207] If approved, the GMM manufacturer can research "only as described in the TERA," or the manufacturer will be subject to "civil and criminal penalties."[208] This exemption applies to research

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[197] *See* 15 U.S.C. § 2604(a)(1)(A)(i); *see also* 40 C.F.R. § 725.150(a) (2019).

[198] 15 U.S.C. § 2602(2)(A)(i).

[199] McKerley, *supra* note 182, at 10 (quoting the Federal Register).

[200] 40 C.F.R. § 725.3 (2019).

[201] *Id.* § 725.100(a).

[202] Wozniak et al., *supra* note 188, at 77.

[203] *Id.* at 77–78.

[204] § 725.200.

[205] *Id.* §§ 725.200(b), 725.250(a).

[206] *Id.* § 725.270(a)(1), (b)(2).

[207] *Id.* § 725.270(b)(4).

[208] *Id.* § 725.270(c)(2)–(3).

and development activities that occur in a closed structure and are funded by another federal agency.[209]

Before 2016, TSCA only required manufacturers to submit the toxicity data they had at the time of filing and did not require extensive testing or safety certification until the manufacturing of the chemical.[210] Without these requirements, thousands of chemicals were manufactured and sold with no safety data.[211] Additionally, the EPA needed actual evidence that a chemical posed a risk before the EPA could require the manufacturer to test the chemical's safety.[212] These lenient requirements limited U.S. chemical companies from selling their products in the E.U. because the E.U. required "all manufacturers, importers, and exporters of chemicals to register such chemicals and to supply basic toxicological information about those chemicals as a precondition to registration."[213] These issues led to the 2016 TSCA Amendments.[214] Now, TSCA requires the EPA to review the GMM's possible impact on potentially exposed or susceptible populations,[215] and manufacturers may not produce their GMMs until the EPA completes this review process.[216] For the manufacturer to begin production, the EPA must determine that the GMM poses no unreasonable risk to human health or the environment.[217] If the GMM poses an unreasonable risk or there is insufficient information to determine if there is a risk, the EPA can condition the manufacturer's production, or it can completely ban production all together.[218]

B. *Regulating Experimental Use*

Before GMMs can facilitate widespread bioremediation, scientists need to further research their actual effects in different environments.[219] However, under the current regulatory scheme, obtaining a government permit to allow the necessary experiments is often difficult and time-consuming.[220] TSCA's premanufacture notice involves several forms for reviewing the potential health and environmental

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[209] *See id.* § 725.232.

[210] PERCIVAL ET AL., *supra* note 26, at 231.

[211] *Our Updated Chemical Safety Law: The Lautenberg Act*, ENV'T DEF. FUND, https://www.edf.org/health/new-chemical-safety-law-lautenberg-act [https://perma.cc/P9GK-A4WW].

[212] *See id.*

[213] PERCIVAL ET AL., *supra* note 26, at 232.

[214] *Id.*

[215] David J. Glass, *Impact of TSCA Reform on EPA Regulation of Industrial Biotechnology*, 12 INDUS. BIOTECH. 204, 204–05 (2016), https://doi.org/10.1089/ind.2016.29041.djg.

[216] McKerley, *supra* note 182, at 10–11.

[217] *Id.*

[218] Wozniak et al., *supra* note 188, at 81–82.

[219] Gary S. Sayler & Steven Ripp, *Field Applications of Genetically Engineered Microorganisms for Bioremediation Processes*, 11 CURRENT OP. BIOTECH. 286, 288 (2000).

[220] *Id.* at 287.

impacts the GMM could cause.[221] Due to the overly laborious process, many researchers are focusing on the commercial production of naturally occurring microbes instead of GMMs.[222] Even the GMMs that the EPA authorizes for experimental field testing are released in a confined and "somewhat artificial system," meaning the test results leave many variables unaddressed.[223]

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") currently addresses the experimental use of GMMs.[224] FIFRA only regulates GMMs in pesticides.[225] Due to the concern that microorganisms will reproduce and multiply in the environment, FIFRA requires an experimental use permit for "small scale field testing" of microbial pesticides.[226] This could readily apply to regulating experimental field testing of GMMs for bioremediation. To obtain an experimental use permit under FIFRA for GMMs, the applicant must also notify the EPA,[227] which must approve the notification before the applicant can begin experimenting.[228] FIFRA also requires a methodology description, the new gene's location, the microbe's new traits and potential for genetic transfer, and overall genetic stability.[229] Once the EPA approves the notification, and after an experimental use permit is obtained (if needed), the experimental field testing can begin. FIFRA requires the permittee to monitor the experiment and submit reports outlining any "unreasonable adverse effects on health or the environment."[230] After experimenting, the permittee must apply again to register the GMM for pesticide use.[231]

FIFRA's experimental use and notification requirements provide a good foundation for experimental testing of GMMs for bioremediation. For *ex situ* bioremediation, experimental permitting would be unnecessary because the remediation would take place in a closed environment.[232] For *in situ* bioremediation, GMM producers would submit a notification for approval to perform small-scale field testing, and after receiving an experimental use permit, they could then perform large-scale field testing.[233] The producer would then submit a report outlining the experiment results, after which the EPA could decide whether to register the GMM for bioremediation.

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[221] *Id.*

[222] *Id.*

[223] *See id.*

[224] *See* 7 U.S.C. §§ 136–136y.

[225] Wozniak et al., *supra* note 188, at 63.

[226] *Id.* at 65.

[227] 40 C.F.R. § 172.45(a) (2019).

[228] *Id.*

[229] *Id.* § 172.48(g)–(j).

[230] *Id.* §§ 172.57, 172.8(a).

[231] Wozniak et al., *supra* note 188, at 70.

[232] *See* § 172.45(d)(2).

[233] *See id.* § 172.3(d).

Requiring an experimental use permit for GMM experimentation would be a first step towards the commercial development and widespread use of GMMs for bioremediation. Implementing a system similar to FIFRA would allow the EPA to directly monitor, approve, and even restrict certain aspects of the experiment. However, if the EPA excessively limits or restricts experimentation, then GMM developers may be unable to gather the information necessary to further develop or commercialize the microbe.

C. *Precautionary Regulations*

The EPA outlines the importance of early and integrated planning for designing a bioremediation system.[234] This planning begins with a site characterization that gathers information such as the amount and type of pollutant, the biodegradation processes of the site's existing microbes, the potential presence of other metabolites as well as aquifers or groundwater, and other ecological data about the specific site.[235] This preliminary data guides the parties responsible for remediating in deciding the best bioremediation process at the specific site.[236] For efficiency, the EPA could implement a registry system that would list the various types of bioremediation available for treating specific hazardous wastes.

Due to the unknown risks of GMMs, Congress should first amend TSCA's MCAN requirements to include GMMs made from introducing lab-created genes, because these are the GMMs that could bioremediate hazardous wastes that current methods cannot.[237] Having MCAN information[238] in the Chemical Substance Inventory can help minimize the uncertainty of using GMMs for bioremediation.

While using TSCA's Chemical Substance Inventory identifies some risks, incorporating the additional data requirements under FIFRA would better address the risks of GMMs in an open environment. Under FIFRA, GMMs are subject to the same data requirements as naturally occurring microbes, but manufacturers must provide additional data about the genetic engineering process.[239] The general data requirements relate to the GMM's toxicology, effect on non-target organisms, and environmental fate.[240] Data requirements may vary based on the microbe's unique qualities.[241] For example, GMM pro-

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[234] GREEN REMEDIATION BEST MANAGEMENT PRACTICES: BIOREMEDIATION, *supra* note 119.

[235] *Id.*

[236] *Id.*

[237] *See generally* SPEIGHT, *supra* note 91, at 296.

[238] 40 C.F.R. § 725.155 (2019).

[239] *Introduction to Biotechnology Regulation for Pesticides*, ENV'T PROT. AGENCY, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/introduction-biotechnology-regulation-pesticides#overview [https://perma.cc/5T5L-348E].

[240] 40 C.F.R. §§ 158.2140–.2150 (2019).

[241] *Id.* §§ 158.100–.130.

ducers must provide toxicology data for every microbial pesticide, but they need not provide specific toxicology such as effects on reproductive health or carcinogenicity, except for certain microbes.[242] Because of the wide variety of GMMs, a similar system showing data requirements would allow GMM producers to provide the required information—and only the information that specifically applies to their GMM. This limit would provide structure and alleviate stress for GMM producers, because they would be free from analyzing every potential risk of their GMM.

After receiving this data, the EPA weighs the benefits the microbe can provide against the "potential adverse effects to non-target organisms; environmental fate of the microorganism; and the potential pathogenicity and infectivity of the microorganism to humans."[243] If using the microbe as a pesticide "will not generally cause unreasonable adverse effects on the environment," then the microbe can be registered for pesticide use.[244] Because pesticides function in an open environment, this registration system provides a good backbone for GMM use for *in situ* bioremediation. Once the EPA determines that a GMM will not cause an unreasonable adverse effect on the environment, the GMM can proceed as a viable technology for treating hazardous wastes.

Another way to regulate GMMs would be requiring biological failsafes to mitigate potential environmental harm.[245] Producers can synthetically modify GMMs to have biological containment systems or genetic safeguards, which are designed to limit a microbe's growth or life span.[246] One example is called engineered auxotrophy, which occurs when a producer develops a GMM without the ability to create an essential compound needed for its survival.[247] For example, a microbe designed to efficiently degrade crude oil also has a gene that makes the microbe unable to live without a certain nutrient. This addresses the concern of GMMs becoming invasive species or transferring their genetic material into the environment, because the microbe will not survive outside the area where the nutrient is provided.[248] Another example of biological containment is called induced lethality, which is a genetic "kill switch" that is engineered into the microbe's genome.[249] The microbe exists normally until a chemical inducer is added, and then the microbe dies.[250] There are also studies that show

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[242] *Id.* § 158.2140.

[243] *Introduction to Biotechnology Regulation for Pesticides*, *supra* note 239.

[244] § 152.112(e).

[245] *See generally* Moe-Behrens et al., *supra* note 19, at 2.

[246] *Id.*

[247] *Id.*

[248] *Id.* at 3.

[249] *Id.*

[250] *Id.*

successful genetic engineering of a monitoring system.[251] The microbe is engineered with bioluminescence genes that effectively make the microbes glow.[252] Glowing microbes are easy to see and record, which allows scientists to cheaply monitor the bioremediation process without adding chemicals.[253]

The EPA could require that GMM producers engineer these biological containment systems into the microbes before the microbes can be used for bioremediation, which could potentially give more freedom for *in situ* bioremediation because the microbes would not need to be physically contained. However, these biological containment methods are not fool proof. Any random mutation can result in deleting or inactivating the engineered containment, which could lead to an accidental release.[254]

After experiments confirm that GMMs are safe for large-scale environmental use, the EPA could adopt a registration system similar to that of FIFRA. Taking this registration system one step further, the EPA could use TSCA's database to register specific GMMs (after successful field trials) as eligible technology for RCRA and CERCLA clean-ups.

D. *Liability Regulations*

The above recommendations focus on meeting certain standards before the actual use of GMMs. However, uncertain risks associated with GMMs could lead to either too much or not enough regulation.[255] To address these uncertain risks, the government could enforce liability on responsible parties after harm occurs.[256]

CERCLA is a retroactive statute that deals with cleaning up mishandled or accidentally released hazardous substances.[257] These are "substances which, when released into the environment may present substantial danger to the public health or welfare or the environment."[258] CERCLA establishes two types of responses: removal actions and remedial actions.[259] Removal actions generally respond to short term or immediate threats or emergencies, such as a chemical spill.[260] Remedial actions generally involve cleaning up hazardous waste sites for complete remediation.[261] The necessary remediation

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[251] Sayler & Ripp, *supra* note 219, at 286.

[252] *Id.* at 287.

[253] *Id.* at 288.

[254] *See* Dangi et al., *supra* note 86, at 90.

[255] McKerley, *supra* note 182, at 23.

[256] *Id.*

[257] PERCIVAL ET AL., *supra* note 26, at 413.

[258] 42 U.S.C. § 9602(a).

[259] Brusseau, *supra* note 77, at 313.

[260] Raker, *supra* note 33, at 1158–59.

[261] *Id.* at 1159.

action depends on the site's status on the Superfund Site Inventory.[262] If the site meets certain qualifications after preliminary assessment and inspections, a National Priorities List will indicate the site as requiring remediation.[263] Then the site goes through a remedial investigation and feasibility study to determine the nature and extent of the risk and to evaluate the best remediation method.[264] The site then remains on the National Priorities List until the site is fully remediated.[265]

After a release of a hazardous substance, CERCLA also assigns liability to four potentially responsible parties: (1) current owners and operators; (2) previous owners and operators; (3) parties who arranged for disposal, treatment, or transport of hazardous substances; and (4) parties who transported the hazardous substances.[266] While CERCLA does not mention specific liability, courts have found that the statute holds responsible parties strictly, jointly, and severally liable.[267] Strict liability relieves the government from needing to prove that the release of the hazardous substance was due to negligence.[268] Additionally, if there are multiple parties involved, all are strictly, jointly, and severally liable unless a party can show that a "reasonable basis for apportionment exists."[269] In *Burlington Northern & Santa Fe Railway Co. v. United States*, the Supreme Court limited a party's liability arising from a chemical spill to the percentage of that party's contribution to the contamination (10%).[270] The CERCLA liability scheme is important because liable parties are responsible for government clean-up costs, damages to natural resources, costs of certain health assessments, and injunctive relief "where a site may present an imminent and substantial endangerment."[271]

If CERCLA governed GMMs, the party responsible for their release could be strictly liable for clean-up costs plus any "injury to, destruction of, or loss of natural resources."[272] This addresses the concern that a field release of GMMs could eventually lead to contaminating the surrounding environment. However, parties that use GMMs for bioremediation may not know as much about the potential risks as either the GMMs' original producers or government agencies.

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[262] Brusseau, *supra* note 77, at 313.

[263] *Id.*

[264] *Id.*

[265] *Id.*

[266] 42 U.S.C. § 9607(a)(1)–(4).

[267] PERCIVAL ET AL., *supra* note 26, at 449.

[268] *Id.* at 450.

[269] Burlington N. & Santa Fe Ry. Co. v. United States, 556 U.S. 599, 614 (2009).

[270] *Id.* at 617.

[271] *Superfund Liability*, ENV'T PROT. AGENCY, https://www.epa.gov/enforcement/superfund-liability [https://perma.cc/3WB9-N4Q5]; *see also* 42 U.S.C. § 9607(a)(4).

[272] *See* § 9607(a)(4)(A)–(D).

Using RCRA's cradle-to-grave liability scheme would address this issue. The cradle-to-grave system ensures hazardous waste is strictly managed from the time it is generated to the time it is treated, stored, or disposed of, including any transportation.[273] RCRA has five main elements: (1) identifying the type of waste being generated; (2) a tracking log describing the waste, quantity, generator, and receiver to monitor transportation; (3) requiring an EPA-issued permit for any facility that treats, stores, or disposes of hazardous waste; (4) EPA standards; and (5) penalties for companies that fail to comply with regulations.[274]

RCRA holds liable any generator, transporter, or owner of a treatment, storage, or disposal facility that has managed hazardous waste which may present an imminent and substantial endangerment to health or the environment.[275] However, RCRA does not expressly state a liability standard, and while circuit courts and legislative history indicate that RCRA imposes strict liability, in practice, courts are less strict and instead examine a party's affirmative conduct or acts.[276] The imminent-hazard provision is essentially a codification of common law public nuisance.[277] This provision should be interpreted liberally to ensure that "problems that Congress could not have anticipated . . . will be dealt with in a way minimizing the risk of harm to the environment and the public."[278] No showing of actual or immediate harm is required.[279] Additionally, there is no statute of limitations under RCRA for pollution liability, meaning the waste generator remains liable for the hazardous waste until its destruction or disposal.[280]

Under this type of liability, producers, transporters, and parties who use GMMs are potentially liable for any accidental release.[281] Cradle-to-grave liability is more restrictive than CERCLA liability because it addresses potential risks in the development-and-use stage instead of only addressing after-the-fact harm. Additionally, the parties that produce the GMMs are likely to have more knowledge about the potential risks than government agencies. Under a liability regulation, these parties are motivated to minimize any potential risks to avoid being financially responsible for any harm caused.

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[273] *Resource Conservation and Recovery Act (RCRA) and Federal Facilities*, *supra* note 34.

[274] Percival et al., *supra* note 26, at 365.

[275] 42 U.S.C. § 6973(a).

[276] Erin Guffey, *RCRA Liability: Not Strict in Application*, 28 Nat. Res. & Env't 46, 46 (2014).

[277] United States v. Waste Indus., Inc., 734 F.2d 159, 167 (4th Cir. 1984).

[278] *Id.*

[279] Percival et al., *supra* note 26, at 408.

[280] King et al., *supra* note 15, at 3–4.

[281] Guffey, *supra* note 276, at 46.

V. CONCLUSION

The continuous industrial growth of the United States has led to the release of numerous hazardous pollutants into the environment, negatively affecting both human health and natural systems. A large portion of these pollutants spread as industrial waste, creating a need for clean and effective waste management, such as remediation. However, current remediation procedures are expensive and produce large amounts of hazardous byproducts, which has in turn led hazardous waste producers to the cleaner and cheaper method of bioremediation. Bioremediation presents an attractive treatment option with major benefits, including a wide scope of application, an undisturbed environment, and the elimination of waste or waste toxicity. Additionally, with the ever-advancing field of biotechnology, researchers can genetically modify microbial populations to target specific pollutants, withstand certain environments, and even die after the remediation is completed.

The current regulatory scheme governing the widespread release of these genetically modified microbes is vague and also rather restrictive. Because of the unknown health and ecological effects, the field release of GMMs is heavily regulated, even for experimentation. These regulations have created a research-commercialization gap, and without adequate field-testing and experimentation, the unknown effects will remain unknown.

Establishing a more lenient regulatory system will allow scientists to better estimate potential risks to human health and the environment. Additionally, more accessible field experimentation can help scientists identify and eliminate issues in GMMs that do not arise in closed laboratory settings. Following successful experimentation, the EPA should implement a registry system that addresses potential risks and lists GMMs as a viable technology for remediating hazardous wastes. The EPA can also manage GMMs under RCRA and hold parties responsible for the accidental release or other unknown dangers that could stem from using GMMs in an open environment.

To further develop GMMs for bioremediation, regulations must allow the bioremediation industry to continue innovating while also protecting human health and the environment. By removing uncertainty and replacing it with comprehensive regulation and requirements, GMMs can enter the commercial sphere and become a potential solution to the ever-increasing issue of hazardous waste.