Meeting the Moment: Opportunities and Limitations for for Genetically Engineered Microbes for Bioremediation

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https://doi.org/10.38126/JSPG260201
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Keywords: Remediation; environmental health; biotechnology; science policy; bioeconomy; regulation

Executive Summary: As anthropogenic compounds are released into the environment at unprecedented rates, there is an ever-growing need for robust remediation strategies. Bioremediation, a method of immobilizing or transforming contaminants, is cost-competitive, environmentally friendly, and effective. With the global bioremediation market anticipated to grow by $8.29 billion between 2023 and 2028, this method of reducing pollutants represents a rapidly expanding sector of the bioeconomy. Millions of tons of pollutants now contaminate soil and groundwater, posing severe threats to human and environmental health. At the same time, as contaminants of emerging concern such as microplastics, pharmaceuticals, pesticides, and per- and polyfluorinated alkyl substances (PFAS) resist treatment with naturally occurring organisms, it may be useful to expand bioremediation's toolkit to include genetically engineered microbes for bioremediation (GEMBs). There has been long-standing interest in developing GEMBs to enable faster remediation times and address a wider range of contaminants. Despite decades of investigation and development of GEMBs, none have been commercialized to date. Historically, the perceived need for GEMBs has not been sufficient to overcome the investment and risk in the context of an uncertain regulatory environment and a paucity of fundamental knowledge of GEMBs. However, as industries, environments, and human health experience disruptions from increasingly recalcitrant, widespread, and hazardous contaminants, the value proposition of GEMBs is more compelling than ever before. The contemporary challenges with managing environmental contamination coupled with advances in genetic engineering methods and renewed interest from researchers, developers, and policymakers signal an opportunity to realize the potential of GEMBs. To support safe and efficient development, characterization, and commercialization of GEMBs as a means of urgently addressing environmental contamination, we propose clarifying and restructuring the risk assessment process for GEMBs, establishing an interagency coordination office, collaboratively addressing critical knowledge gaps, and leveraging public-private partnerships.

I. Introduction

Environmental contamination is a global issue with far-reaching consequences for human and environmental health. In addition to rendering land and water unusable, harmful contamination contributes to millions of premature deaths each year (Münzel et al. 2022). Contaminants of emerging concern (CECs) are "chemicals or materials characterized by a perceived, potential, or real threat to human health or the environment or by a lack of published health standards" (Connecticut DEEP 2023). The threats posed by CECs stem not only from their unprecedented abundance in the environment, but also from their increasing novelty, diversity, and complexity. Thousands of CECs have been introduced to the environment only within the last century (Naidu et al. 2021). The health effects and environmental fate of these compounds often come to light only after widespread distribution; for instance, per- and polyfluoroalkyl substances (PFAS), some of which have now been linked to serious health issues, are used in hundreds of products and are easily accumulated in the environment (Kirk et al. 2018). Contamination disrupts industries, supply chains, and treatment processes. Maine and Connecticut recently issued total bans that limit the resale and application of wastewater treatment end products, which are frequently applied to soil, after discovering the practice was contaminating wide swaths of farmland with PFAS (Wallace 2024). Reducing contaminant concentrations to acceptable levels now poses a significant challenge for the waste treatment and remediation industries.

Contaminated sites are heterogeneous, and there is no one-size-fits-all approach to remediation; therefore, a diversified toolkit is essential for addressing contamination. Bioremediation itself is a toolkit rather than a single method. If contaminant-degrading microbes are already present at a remedial site, their native activity can be stimulated by adding nutrients to the system (biostimulation). Alternatively, active cultures of microbes can be introduced to the impacted area (bioaugmentation). Bioremediation is frequently favored as an environmentally friendly, cost-competitive, and minimally invasive treatment option relative to physical and chemical remediation strategies (Kuppan et al. 2024). Despite these significant advantages, its applicability and efficacy can be limited by long treatment times, the possibility of generating secondary pollution, and the recalcitrance of some compounds—especially applicable to CECs—to biological degradation with naturally occurring microbes (Khalid et al. 2017; Rebello et al. 2021).

Genetic engineering may offer a route of enhancing bioremediation, though this route remains underexplored. Microbes could be engineered to enable faster degradation rates, preferred biotransformation pathways that avoid secondary pollution, and greater tolerance to toxicity from CECs or metabolites. Additional capabilities such as biosensing could also be incorporated to enable simultaneous bioremediation and monitoring of the process. Early studies of genetically engineered microbes for bioremediation (GEMBs) have demonstrated promise in these areas (Bigley et al 2019; Rebello et al. 2021; Sayler and Ripp 2000; Shimazu et al. 2001). Nevertheless, while numerous GEMBs have been developed in laboratory settings, no GEMBs have been commercialized in the United States to date. The regulatory environment is frequently cited as a major barrier to implementing genetically engineered microbes in the US due to its fragmentation across agencies and the varying, but often steep, risk assessment requirements despite limited resources for GEMB development (Chemla et al. 2024; Ezezika and Singer 2010; Rebello et al. 2021; Jansson, McClure, and Egbert 2023; Hu et al. 2022). This brief explores this regulatory landscape and the factors complicating the evaluation, development, and use of GEMBs. We identify a few specific challenges and provide recommendations for clarifying and supporting the development of GEMB application pathways in the United States bioeconomy.

II. Regulatory Landscape for GEMBs

A multitude of regulatory statutes overseen by diverse agencies may apply to GEMBs (see Table 1 for an overview), depending on the biological construct of the organism and intended application space (e.g., added *in situ*, or directly to a contaminated environment or *ex situ*, such as in an external treatment process). This brief is primarily concerned with *in situ* GEMB deployment, as GEMB use in contained environments overseen by a technically qualified individual may be exempt from reporting requirements; however, the applicability of a given statute to *in situ* or *ex situ* GEMB use is indicated in Table 1. Pursuant to the Coordinated Framework for Regulation of Biotechnology, genetically modified organisms are regulated based on product categories and uses (51 FR 23302; June 26, 1986). GEMBs are primarily regulated by the EPA under the Toxic Substances Control Act (TSCA), which applies if the GEMB is "intergeneric, manufactured or processed for commercial production purposes, including R&D for commercial purposes, for a use that is not excluded under TSCA, and is not otherwise exempt from reporting" (51 FR 23302; June 26, 1986; 15 U.S.C. §2601–2692, 1976). Under TSCA, the EPA has the authority to mandate testing, reporting, restrictions, and testing requirements for chemical substances and/ or mixtures. As a novel agent or an established GEMB being considered for a "significant new use," TSCA compliance may involve the collection of field trial data or the submission of an environmental release application.

Other statutes may apply as well, falling variably under the authority of EPA, FDA, or USDA. The National Environmental Policy Act (NEPA) requires federal evaluation of actions taken by agencies to ensure they do not cause environmental harm (42 U.S.C. § 4321 et seq. 1970). GEMBs used in waste treatment systems that may be discharged or otherwise enter waters of the US may also be subject to EPA regulation under the Clean Water Act (CWA) (33 U.S.C. §1251 et seq. 1972). Such microbes must be TSCA-compliant, and additional data relating to discharge concentrations may be required. The EPA may also oversee requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) if the GEMB is considered a pesticide (7 U.S.C. §136 et seq. 1996). The Resource Recovery and Conservation Act/ Comprehensive Environmental Response, Compensation, and Liability Act (RCRA/ CERCLA) may be relevant for the disposal of GEMBs if they meet the criteria for hazardous waste (42 U.S.C. § 6901 et seq. 1976). The Endangered Species Act (ESA) may apply in cases where a GEMB is being considered for the remediation of an environment that contains or provides habitats for classified endangered species (16 U.S.C. §1531 et seq. 1973). Under ESA, a mitigation plan to reduce potential negative effects to endangered species is required.

The USDA may also be involved in the regulation of GEMBs if certain conditions are met. For instance, the USDA is responsible for evaluating the potential plant pathogenicity of a GEMB under the Plant Protection Act (PPA) depending on the construction and sourcing of the GEMB (7 U.S.C. §7701 et seq. 2000). If a "Findings of No Significant Impacts" is not reached under PPA, the National Environmental Policy Act (NEPA) mandates an environmental impact statement (EIS) review (43 U.S.C. § 1638 et seq. 1980). Permitting from the Plant Protection and Quarantine Program (PPQ) may also be required if deployment of the GEMB involves interstate movement. Finally, pursuant to the Food, Drug, and Cosmetic Act (FDCA), the Food and Drug Administration (FDA) may become involved in the regulation of a GEMB to assess exposure risks (21 U.S.C. §301 et seq. 1938).

III. Challenges for GEMB Regulation and Use

The current regulatory and development landscape for GEMBs suffers from a few central challenges. First, as we have summarized, the regulatory landscape for potential applications is complex and there are several potential trigger points. The lack of precedent for the release of GEMBs into any environment means that regulatory pathways for many of these applications have not yet been clarified. In addition, applications in one environment, like soil, may have implications for the spread and persistence of the GEMB and its genetic elements into other environments, like groundwater (Sayler and Ripp 2000; Sayre 1997). Furthermore, GEMBs may not be subject to federal regulatory review provided they avoid triggering the statutes summarized in Table 1, yet state and local agencies may impose their own regulatory requirements, creating additional ambiguity for developers. This creates an uncertain regulatory environment for GEMBs.

Second, evaluations of the risk of GEMBs may prove to be too narrow and inhibitory of beneficial applications. Critics of the original proposed Coordinated Framework (reference) expressed concern over a "process-based" approach to

Table 1: Agencies, Statutes, and Requirements for Regulating GE and Non-GE Microbes for Bioremediation. "ES" refers to a statute that applies to a closed system (*ex situ*) and "IS" refers to a statute that applies to an open system (*in situ*). FWS = Fish and Wildlife Service; NOAA = National Oceanic and Atmospheric Administration; OPP = Office of Pesticide Programs; OPPT = Office of Pesticide Programs or Office of Pollution Prevention and Toxics; BRS = Biotechnology Regulatory Services; APHIS = Animal and Plant Health Inspection Service.

Statute	**Responsible Agencies and Offices**	**Purpose**	**Applicability and Requirements Triggered**
Toxic Substances and Control Act (TSCA)	EPA (OPPT)	Prevents unreasonable harm to human health or the environment from the manufacture, processing, use, distribution, and disposal of chemicals; lists novel chemicals including microorganisms.	(IS, ES) The microbe is not a pesticide, is novel or is being proposed for a "significant new use" ● Submission of Premanufacture Notice (PMN) or Microbial Commercial Activity Notice (MCAN) ● Field data may be required ● Environmental Release Application (TERA) may be required The microbe involves interstate movement ● BRS/PPQ permitting may be required
National Environmental Policy Act (NEPA)	EPA (OPPT); USDA (BRS under APHIS)	Mandates federal evaluation of environmental impacts of significant changes to policy or adoption.	(IS, ES) The microbe is constructed from a pathogenic species, is sourced outside of the US or produces a select agent ● Environmental Impact Statement review The microbe is not intergeneric, not proposed for significant new use, but will involve interstate movement ● BRS/ PPQ permitting may be required The microbe is intergeneric ● See requirements under TSCA
Federal Insecticide, Fungicide, Rodenticide Act (FIFRA)	EPA	Prevents unreasonable deleterious impacts to the environment from insecticides, fungicides, and rodenticides. Evaluates the benefits versus risks of	(IS, ES) The microbe is a pesticide ● Registration of novel pesticidal modes of action ● Biotechnology Notification Field Data may be required

Statute	**Responsible Agencies and Offices**	**Purpose**	**Applicability and Requirements Triggered**
		pesticide use with regard to human health and the environment.	● Experimental Use Permit may be required The microbe may come into contact with food/ feed products ● See FDAC requirements The microbe was sourced outside of the US or is a plant pathogen ● See PPA requirements The microbe is intergeneric ● See TSCA requirements
Clean Water Act (CWA)	EPA	Regulates discharge of pollutants into waters of the U.S., establishes water quality standards, sets industry standards for wastewater treatment.	(IS, ES) The microbe is regulated or produces a compound regulated by water quality standards ● May require data collection to determine compliance with Total Maximum Daily Load plans The microbe is for use in a waste/ wastewater treatment system ● See TSCA requirements
Endangered Species Act (ESA)	FWS; NOAA Fisheries; EPA (OPP)	Prevents federal agencies from approving actions that may threaten classified endangered species or their habitats.	(IS) GE or non-GE microbe being considered for remediation use in an environment with classified endangered species ● Mitigation plan
Resource Conservation and Recovery Act (RCRA)	EPA	Structures the management of hazardous and non-hazardous solid waste, guides cleanups based on environmental indicators.	(IS, ES) The microbe is considered for the remediation of a contaminated site ● Assessment of the remediation potential in a Corrective Measures Study The microbe qualifies as hazardous waste ● Permit may be required for treatment, storage, or disposal of the microbe

Statute	**Responsible Agencies and Offices**	**Purpose**	**Applicability and Requirements Triggered**
Comprehensive Environmental Response Compensation and Liability Act (CERCLA)	EPA	Directly responds to released or potentially released hazardous waste that may impact public health or the environment, guides short-term and long-term cleanups.	(IS, ES) The microbe is considered for the remediation of a contaminated site ● Assessment of the remediation potential in a Feasibility Study The microbe qualifies as hazardous waste ● "Potentially responsible parties" for the microbe's release may be held liable for cleanup costs
Plant Protection Act (PPA)	USDA (BRS under APHIS)	Protects agriculturally-relevant plants and natural resources from actual or possible plant pathogens or noxious weeds.	(IS) The microbe is constructed from a plant pathogen, has potential for plant pathogenicity ● Submission of an "Am I Regulated?" inquiry ● Environmental Impact Statement review may be required The microbe will be transported across state lines ● BRS/ PPQ permitting may be required
Federal Food Drug and Cosmetic Act (FFDCA)	FDA; EPA (OPP)	Prevents harm from aggregate exposure to pesticide chemical residues.	(IS, ES) The microbe may come into contact with food, poses a risk to plants or animals ● Environmental Impact Statement review The microbe is intergeneric ● See TSCA requirements

regulating genetically engineered microbes, citing insufficient links between development process and novelty and risk and the potential for bias against novel techniques, even if they may be safer or more advantageous than their traditional counterparts (Colwell et al. 1987; 51 FR 23302; June 26, 1986). In response, the EPA ultimately identified three foci for evaluating microorganisms under TSCA and FIFRA: use in the environment, pathogenicity or construction from pathogens, and the expression of novel combinations of traits (i.e., intergeneric) (51 FR 23302; June 26, 1986). Regulatory attention on the three aforementioned qualities was intended to enable risk-based classification of microorganisms but this approach does not entirely avoid the pitfalls ascribed to a process-based regulatory approach. For example, microbes with DNA from other organisms (i.e., intergeneric) are automatically subject to heightened scrutiny despite evidence that they are not inherently higher risk. (Carter et al. 2014;

Colwell et al. 1987; Marken, Maxon, and Murray 2024).

Third**,** the deployment context of GEMBs is generally designated as contaminated environmental sites that have been deleteriously impacted by pollutants. Further minimal environmental disturbance is undesirable in these spaces, however remediation actions are needed to facilitate the protection of human and environmental health, reduction of contaminants, and restoration of land use and functionality (Ridsdale and Noble 2016). Thus, the potential risks and benefits of applying GEMBs must be weighed against the hazards posed by the existence of the contaminated environment. A precedent for such analysis already exists within the structure of U.S. federal agencies in the "no-action alternative", which directs federal agencies under NEPA to consider the potential impact of not approving a proposed action, like deploying genetically engineered microbes (Chemla et al. 2024). In the case of a hypothetical GEMB, not approving its use could result in pollutants causing more widespread damage or the selection of a less efficient or safe remediation approach[1,2]. Currently, there is no central criteria for the no action alternative, and the EPA is not currently required to consider a no-action alternative during regulatory review (Chemla 2024). A requirement and more specific criteria for considering the no action alternative could result in a more complex analysis of hazards and benefits of GEMB applications than the current assessment approaches.

Lastly, GEMB development is hindered by a lack of federal support and research and testing infrastructure. Historically, the US government has funded some infrastructure and research into GEMBs and other genetically engineered (GE) microbes designed for environmental release. In 1984, the Biotechnology Research Program set forth by the EPA emphasized studies on environmental exposure, environmental effects, and control of microbes designed for environmental release (EPA 1994). Infrastructure and support for basic research yielded numerous studies on the spread, survival, gene transfer, and ecological interactions of released microbes, as well as control and mitigation strategies. However, a convergence of factors including lackluster performance results of early technologies, intellectual property concerns, and broader social controversy over applications of GE organisms has limited development progression over time (Evans 2020). Fundamental questions regarding the fate, transport, and ecological risks of GEMBs remain, but they are difficult to address considering the lack of research and testing infrastructure available today.

A renewed interest in developing GEMBs signals an opportunity to address some of these regulatory and infrastructural challenges. The past few years have seen a steady flow of publications showcasing newly-developed GEMBs and novel approaches for engineering individual microbes and microbial communities for bioremediation (French et al. 2020; Hu et al. 2022; Rubin et al. 2021). Recent high-profile review articles emphasize the opportunities for genetic engineering in combating pollution and affirm the need for supportive infrastructure and clarified regulations (Jansson, McClure, and Egbert 2023; Johnson 2024). Some companies are pursuing GEMB development despite the challenging regulatory and commercial environment. One such example is Allonnia which received a $20 million investment in 2021 to optimize microbes for bioremediation using synthetic biology (Walsh 2021). This activity indicates a new wave of GEMB development equipped with more mature genetic engineering tools and a greater environmental need for GEMBs than in decades prior.

IV. Policy Recommendations

i. Consider GEMB context and construction to streamline risk assessments

As currently formulated, risk assessments constitute a major bottleneck in the GEMB development

[1] For instance, in addition to pollution threatening the health of humans, animals, and the environment, studies indicate pollution can trigger stress responses and shifts in microbial community structure, often favoring pathogenic microbes (Guerra et al. 2021; Wang et al. 2023; Huo et al. 2024). It has been suggested that the introduction of microbes capable of pollutant biodegradation can help alleviate this stress, enabling the microbial community to better protect itself and more effectively degrade pollutants (Muter 2023).

[2] Alternative remediation methods include excavation, air stripping, incineration, chemical oxidation, solidification, etc. Though accepted, these methods can result in significant disturbance to the environment, high monetary and energy demand, and the generation of secondary pollution while not necessarily destroying contaminants (Sahl and Munakata-Marr 2006; Cappuyns 2013).

pipeline. We recommend several ways to streamline the regulatory process without sacrificing safety. Most straightforwardly, echoing the critiques of intergenericity, namely that it is a poor indicator of risk or novelty, we suggest eliminating this regulatory trigger (Carter et al. 2014; Colwell et al. 1987; Marken, Maxon, and Murray 2024). Secondly, as a means of enabling more nuanced consideration of hazards and benefits, we recommend developing requirements and central criteria for the “no action alternative”. The NEPA criteria for the no action alternative is currently a vague set of criteria that needs to be clarified and centralized in the evaluation of GEMB applications. Review should include consideration of the potential financial, socio-economic, public health, and ecological impacts of proposed actions with GEMBs, and compare those to no-action alternatives and scenarios that use non-GEMB approaches. A case by case approach may be best for this analysis, as the risks and benefits with respect to financial, socio-economic, and ecological elements may all vary across different contexts. However, we strongly recommend that the no-action alternative become a requirement for EPA review under TSCA and FIFRA, especially for applications of GEMBs in significantly contaminated environments. Analysis through the no-action alternative could help clarify the ideal application context for GEMBs, especially in cases where other approaches to remediation have failed or proved implausible.

We recommend that regulatory agencies develop guidelines specifying the ideal context of use to provide a cue to researchers and developers on what spaces are most appropriate for applications of GEMBs. Context of use (COU) is a concept used in other regulatory situations such as the FDA’s regulation of biomarkers used in drug development. The COU requires a concise description of the biomarker category and how it is linked to an ideal set of intended uses in drug development (FDA 2021). Agencies like the EPA could transpose the COU concept to the GEMB context by developing categories of GEMBs that are linked to intended uses in different polluted environments. This could help distinguish between GEMB functions (i.e., biosensing, biostimulation, or bioaugmentation) across different environments (i.e., soil, water, air, built environment) and allow agencies like the EPA to clarify which applications are subject to which regulations depending on the category of GEMB and intended use.

Greater coordination between regulators and developers may also facilitate a more efficient risk assessment. To this end, we recommend developing a risk-based classification system to inform GEMB construction. Some microorganisms regulated under TSCA may contain incredibly diverse and novel genes, but GEMBs can also be constructed with minimal novelty. For example, the use of indigenous soil microbes as chassis has been suggested to improve bioremediation outcomes, as the stability of a microbial community can make it difficult for introduced microbes to persist (Dechense et al. 2005). Existing GEMBs suggest a preference for improving, overexpressing, or repositioning existing catabolic proteins (Rebello et al. 2021). Using indigenous chassis and existing catabolic proteins as starting points may decrease the risks associated with introducing a novel organism to an environment. A risk-based classification system for chassis, genetic parts, and degree of novelty could encourage the use of indigenous chassis and low-risk modifications as well as expedite the assessment process (Marken, Maxon, and Murray 2024). Such a system could promote alignment of GEMB developers and regulatory authorities earlier in the development process and enable more thorough characterization of favorable chassis and genetic elements to the benefit of all stakeholders. Nevertheless, this system would be limited by the extent of knowledge on GEMBs, which we address in Recommendation 3.

ii. Assign an interagency coordination office to support GEMB development

To effectively and responsibly support GEMB development and implementation, federal agencies will need to coordinate with one another on issues in strategic planning, funding, and risk assessment tasks. We recommend that an interagency coordination office be established to carry forward this work. Our recommendation dovetails with Title IV “Bioeconomy Research and Development” of the 2022 CHIPS and Science Act, which stipulates that the Office of Science and Technology Policy (OSTP) will implement the National Engineering Biology Research and Development Initiative (NEBRDI). This initiative lays out several goals and actions for federal agencies (e.g. USDA, EPA) and departments (e.g. DOE, DoD) to take in supporting research, development, and commercialization of applications for engineering biology (HR 4346, 2022). One important action is to create an Initiative Coordination Office (ICO) which would be responsible for serving as the point of contact on federal activities related to the NEBRDI. Specifically, the ICO would be responsible for promoting "access to, and early application of the technologies, innovations, and expertise derived from Initiative (NEBRDI) activities to agency missions and systems across the federal government, and to the United States industry, including startup companies." (HR 4346, 2022). This call for an ICO in NEBRDI is echoed in the recent report published by the National Security Commision on Emerging Biotechnology, which calls for a National Biotechnology Coordination Office (NBCO) to advise on matters of developing and coordinating a national biotechnology strategy in the United States (NSCEB 2025).

An ICO or NBCO could provide crucial services circulating information and expertise directed towards supporting strategic planning and investments for research and development on GEMBs. In addition, an ICO or NBCO could also support companies and federal agencies during the risk assessment and product review processes for GEMBs. To support companies, an ICO or NBCO could make available important information and expertise to help developers better understand the hazards and risks associated with their products. To support federal agencies, an ICO or NBCO could provide direction and clear up uncertainties related to when and how different federal statutes apply to different applications of GEMBs and support the agency review process by providing supplementary expertise and guidance. This idea already has some traction in the scientific and policy research community as an option to more efficiently delegate regulatory authority on a case-by-case basis for GEMBs, depending on their context of use and exact product classification (e.g. soil amendment, biofertilizer, etc) (Marken, Maxon, and Murray 2024).

iii. Strategically address critical knowledge gaps by developing a research agenda and promoting non-competitive data sharing

To help advance GEMBs, a robust ecosystem for identifying priorities for basic and applied research agendas and developing infrastructure for field trials and safety testing. Scoping out research agendas and developing infrastructure does not need to start at square one, however. In 1988, the Office of Technology Assessment (OTA) developed a report outlining several important priorities for research and testing genetically engineered microbes called "Field Testing Engineered Organisms: Genetic and Ecological Issues". They include 1) testing systems (i.e. aquatic or terrestrial) in laboratory settings to gather essential information on potential consequences of environmental release, 2) understanding in depth the natural history, genetic characteristics of candidate microbes, and their interactions within natural and managed microbial communities, and 3) developing more efficient and convenient post-release monitoring techniques (OTA 1988). Many of these priorities align with more recent calls for enhanced research and testing for GEMBs to help expedite future risk assessments and mitigate the risks of releasing the organism (Marken, Maxon, and Murray 2024; Jansson, McClure, and Egbert 2023; Rycroft et al. 2019). As these research priorities are addressed, we recommend that non-competitive field trial data be published in a centralized, standardized database to further reduce the testing burden on developers and contribute to the establishment of risk assessment baselines for GEMBs.

iv. Leverage public-private partnerships to support development of GEMBs

Research and development for GEMBs would ideally be supported financially by federal programs outlined under the NEBRDI. However, support for this initiative has been delayed due to multiple agencies having not received the full amount of funding needed to fully launch requisite programs and projects (Hourihan and Gordon 2024; Jeffery 2024). Public-private collaboration between private developers and public universities could jumpstart certain agendas and initiatives, such as the creation of research centers and testing facilities focused on work with GEMBs (Marken, Maxon, and Murray 2024). Specifically, developers who have a vested interest in the outcomes of field trials, but not the expertise or space to conduct field trials on GEMBs could benefit from partnering with universities. Universities who are interested in breaking ground on GEMB research but lack access to federal funding would benefit from enhanced financial support from private entities. Some examples of these partnerships exist today, most notably in the agricultural sector. Similar resource sharing across public universities and private companies has helped support research and development across multiple fields, including crop biotechnology (Dowd-Uribe et al. 2024; Markell et al. 2020; Moreddu 2016). Further, unique partnerships between universities, companies, and state-funded extension agencies have paved the way for field trials with new crop biotechnologies and help support the adoption of those technologies. A new kind of public-private coalition could adapt this partnership model to the GEMBs space as a proactive move to then garner further means of federal support in the future once delays in authorizing NEBRDI programs subside.

V. Conclusion

Despite decades of interest in the promise of GEMBs, the development of the technology remains hindered by regulatory uncertainty, lack of federal support, and a paucity of research and testing infrastructure. To regulate GEMBs in a way that maximizes the potential for beneficial outcomes yet minimizes hazards, it is essential to take into account the unique context and construction of GEMBs. The development of infrastructure to align research priorities, enable basic research, and financially support GEMB development would help bridge the gap between interest in GEMBs and their successful commercialization. Specifically, an interagency office may be an effective way to improve communication and coordination between GEMB regulators and developers. Together, a clarified regulatory environment, supportive infrastructure, and interagency office could help enable a potentially transformative, societally beneficial biotechnology in the emerging bioeconomy.

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Acknowledgements

A special thanks to Dr. Emma Frow for providing helpful comments and feedback during the conceptualization and publication of this article. This work was supported in part by a National Science Foundation Grant #2124307, "Collaborative Research: Toward lifelike synthetic cells via engineered control of DNA replication"