United States Government Accountability Office

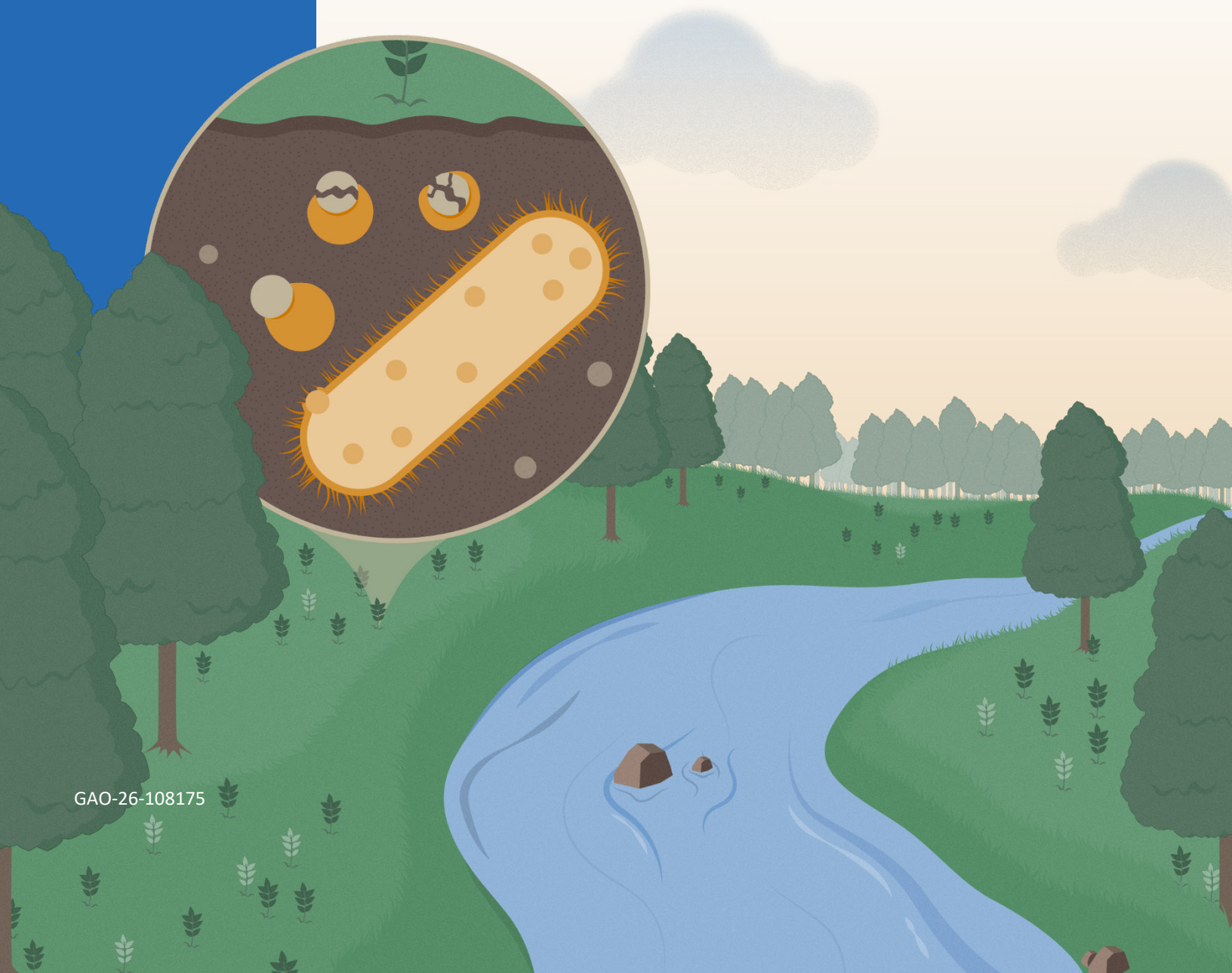
Report to Congressional Addressees

July 2026

TECHNOLOGY ASSESSMENT

Biotechnology

Applications, Challenges, and Policy Options for Engineered Microbes for Waste Cleanup



GAO-26-108175

The cover image displays a stylized representation of a microbe secreting enzymes to break down contaminants in the environment.

Cover source: GAO. | GAO-26-108175

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Highlights of GAO-26-108175, a report to congressional addressees

July 2026

Why GAO did this study

Contamination of land and water with waste chemicals poses significant threats to human health, the economy, and the environment. Research has shown that microbes can be engineered to break down these chemicals, potentially offering promise for cleanup in multiple sectors, including defense, mining, agriculture, and manufacturing.

GAO conducted an assessment of current and emerging engineered microbe technologies for waste cleanup. This report examines (1) the status, benefits, and risks of engineered microbes for waste cleanup, (2) the challenges of developing or using engineered microbes for waste cleanup, and (3) options policymakers could consider to achieve various goals related to this biotechnology.

To conduct this work, GAO reviewed scientific reports and federal agency documents. GAO also interviewed federal agency officials and 25 other experts from academia, industry, and nonprofit organizations. GAO is identifying policy options in this report.

View GAO-26-108175. For more information, contact Sarah Harvey at HarveyS@gao.gov.

What GAO found

Certain types of waste are particularly pervasive or difficult to clean up with existing technologies. Microbes (e.g., bacteria, fungi) can be engineered to break down pollutants more effectively. For example, researchers have inserted genes into bacteria that allow the bacteria to break down contaminants, such as phenol or hydrocarbons, in water and soil. At present, there are no examples of commercially available engineered microbes for waste cleanup.

Example areas where engineered microbes could be deployed for waste cleanup

Source: GAO analysis; (photos left to right) littlewolf1989, IbrahimAlkan, timofeev, Александр Беспалый, kanzefar, juliasudnitskaya, jukuraesamurai/stock.adobe.com. | GAO-26-108175

Through expert interviews and document reviews, GAO identified two policy goals related to this biotechnology—demonstrating safety and effectiveness and developing a market. GAO identified challenges hindering these goals, including:

Insufficient testing infrastructure and standards. The current testing infrastructure and standards are insufficient to scale experimentation beyond the lab or to assess the safety and effectiveness of engineered microbes.

Regulatory catch-22. According to experts, when authorizing experimental release, the Environmental Protection Agency (EPA) requests information that is difficult to obtain without experimental release. EPA officials told GAO that information from published studies or lab data can suffice for permitting experimental release.

Unclear regulatory roles and responsibilities. According to GAO's research, developers lack clarity about the regulatory process for engineered microbes. For example, it is often not clear to developers which agency is responsible for regulating a given engineered microbe and why. EPA officials told GAO, however, that they get very few questions regarding jurisdiction.

Public concerns. Developers may hesitate to invest in research and development of the technology if there is not sufficient public support. Public concerns include the potential for persistence in the environment, possible health effects, and discomfort with manipulating and patenting genetic material.

Based on review of scientific reports, agency documents, and expert interviews, GAO developed 10 options that policymakers could consider if they wish to advance the two goals identified above (demonstrating safety and effectiveness of or developing a market for engineered microbes for waste cleanup). GAO also considered the policy goal of pursuing alternatives to this biotechnology and developed three options policymakers could consider to achieve that goal (not shown on this page; see chapter 5). The following table shows selected policy goals and policy options. See tables 2–8 in the full report for additional policy options and details.

Selected policy goals and policy options related to engineered microbes for waste cleanup

Policy option	Opportunities	Considerations
Policy Goal: Demonstrating safety and effectiveness		
Establish databases to share noncompetitive field trial data among developers (report page 21).	• Could decrease risk in technology development and accelerate product development. • Could reduce testing burden on developers.	• Efforts may be limited by developers' willingness to share proprietary data. • Specific data about government owned sites may be sensitive.
Update legal requirements and associated guidance documents (report page 23).	• Could provide a scaled approach to regulations for small-scale research and better enable research on engineered microbes for environmental release. • Updated regulations may remove the requirement to conduct a regulatory review based on intergeneric genetic changes.	• Updates may not be necessary if agencies can provide better guidance or a coordinating office (see below) to help developers navigate the regulations. • Changes may add significant time or burden on regulatory agencies.
Policy Goal: Developing a market		
Establish a national office for biotechnology coordination (report page 26).	• Could serve as a first point of entry for developers of biotechnologies seeking information on how regulations apply to them. • Could provide greater clarity on and assistance with navigating regulations that apply to specific biotechnology products, including engineered microbes. • Could reduce burden on agencies by taking on specific functions, such as public outreach and coordination among agencies. • Congressional action could provide more stability than executive action, which can be rescinded by a new administration.	• Could add another step, further delaying the regulatory review process. • Will require resources. • Agencies may object to another entity making legal determinations about which agency has regulatory authority in a given matter. • Each agency would still have to follow their individual statutory requirements.
Provide community education (report page 29).	• Could improve public literacy and understanding of new technologies, promoting informed decision making about the use of engineered microbes. • Could improve public understanding of the effects of waste and contamination in the environment, which may increase interest in cleanup efforts.	• May require substantial resources to implement. • May not be as effective as efforts that prioritize engagement.

Source: GAO. | GAO-26-108175

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Abbreviations

DOD	Department of Defense
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
MCAN	Microbial Commercial Activity Notice
NIST	National Institute of Standards and Technology
PFAS	per- and polyfluoroalkyl substances
TERA	TSCA Environmental Release Application
TNT	2,4,6-trinitrotoluene
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture

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July 14, 2026

The Honorable Stephanie Bice
House of Representatives

The Honorable Chrissy Houlahan
House of Representatives

The Honorable Ro Khanna
House of Representatives

Contamination of land, water, and air with certain waste products poses significant threats to human health, the economy, and the environment. For example, U.S. Geological Service researchers estimated in 2024 that approximately 80 million Americans rely on drinking water sources contaminated with per- and polyfluoroalkyl substances (PFAS), a group of chemicals linked to adverse health effects.[1]

Bioremediation, or the use of microorganisms (like bacteria and fungi) to address contaminants, can be a relatively cost-effective and environmentally friendly cleanup technique that could lessen human exposure to hazardous substances.[2] Microorganisms—or microbes—can digest certain contaminants to produce less harmful byproducts like gases and water.[3] Conventional forms of bioremediation are in use today. For example, microbes are used in wastewater treatment facilities to break down organic waste and on oil spills to break down petrochemicals. However, naturally occurring microbes and other remediation methods, such as incineration, cannot break down all types of pollutants.

Advances in biotechnology could help to address the limitations of conventional bioremediation. Engineered microbes are microorganisms that have been genetically engineered or otherwise manipulated for a specific purpose. Researchers and developers are investigating the use of engineered microbes for waste cleanup by engineering them in the lab to break down pollutants for which there are few feasible solutions and to improve on the efficacy and specificity of current bioremediation methods.

[1]A.K. Tokranov, et al. "Predictions of groundwater PFAS occurrence at drinking water supply depths in the United States," *Science*, vol. 386 (2024).

[2]"Remediation" and "bioremediation" include methods that break down or inactivate harmful substances. In this report, we use the term "cleanup" as a synonym for remediation, although in some cases the harmful substances are not removed but rather rendered less harmful. Other organisms, such as plants, can also be used for bioremediation.

[3]The term "microorganisms" is used in regulatory language e.g., 40 C.F.R. Part 725, but it is synonymous with "microbes," which is used more in the industry and in science. We use "microbes" throughout this report.

Engineered microbes hold promise to improve cleanup capabilities across multiple sectors, including defense, mining, agriculture, and manufacturing (see fig. 1).[4] For example, researchers are exploring using engineered microbes at military bases to break down explosives such as 2,4,6-trinitrotoluene (TNT). Researchers have also engineered microbes to degrade plastic into smaller chemical building blocks, which can then be used to make new plastic. Engineered microbes have been used in other fields, for example to develop therapeutics for treating diseases. Several challenges, including concerns about potential risks, hinder their development for waste cleanup.

Figure 1: Example areas where engineered microbes could be deployed for waste cleanup

Source: GAO analysis; (photos left to right) littlewolf1989, IbrahimAlkan, timofeev, Александр Беспалый, kanzefar, juliasudnitskaya, jukuraesamurai/stock.adobe.com. | GAO-26-108175

GAO has previously reported on the use of engineered microbes in recycling, medicine, agriculture, manufacturing, and conservation.[5] We prepared this report at the initiative of the Comptroller General in light of congressional interest in biotechnology. It examines

1. the status, benefits, and risks of engineered microbes for waste cleanup;
2. the challenges of developing or using engineered microbes for waste cleanup; and
3. options policymakers could consider to achieve various goals related to this biotechnology.

[4]Pesticide applications of engineered microbes are not within the scope of this report.

[5]GAO, *Science and Technology Considerations for Maintaining U.S. Competitiveness in Quantum Computing, Synthetic Biology, and Other Potentially Transformational Research Areas*, GAO-18-656 (Washington, D.C.: Sept. 26, 2018) and *Science & Tech Spotlight: Synthetic Biology*, GAO-23-106648 (Washington, D.C.: April 17, 2023).

To address these objectives, we conducted a systematic search and review of selected literature; reviewed federal agency guidance on the development and deployment of relevant technologies; and interviewed federal agency officials and other experts from technology companies, universities, research institutes, and nonprofit organizations. We conducted individual interviews with 25 experts. We selected experts based on their expertise in at least one area related to our objectives, such as technical expertise in microbial engineering or policy expertise related to regulating engineered microbes. We also convened three cross-sectoral discussion groups of seven to nine of these experts.[6] See appendix I for the full objectives, scope, and methodology used in this report and appendix II for the list of experts.

We conducted our work from February 2025 through July 2026 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to technology assessments. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations to our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for the findings and conclusions in this product.

[6]A total of 14 experts participated in these discussion groups.

1 Background

1.1 Why develop new technologies to remediate waste?

Certain types of waste are particularly pervasive as environmental contaminants or difficult to clean up with existing technologies. For example, PFAS are widely dispersed in the environment and have a carbon-fluorine bond, one of the strongest chemical bonds in nature, which causes them to persist in the environment for many years. Other types of waste, such as plastics and pharmaceutical waste are also common in some environments and are being produced more quickly than current remediation technologies can handle. Methods currently used for waste management and cleanup include landfilling, chemical remediation, physical treatments, and conventional bioremediation (using naturally occurring microbes) (see text box).

Conventional remediation methods currently used for waste management and cleanup

The United States treats, stores, and disposes of different types of waste through a variety of processes. Some of these include:

Landfilling waste by burying it or otherwise storing it in planned sites. Advantages include comparative convenience and the potential to reclaim methane as an energy source. Disadvantages include finite land available for landfilling and the possibility of leaks or leaching.

Chemical remediation is the use of chemical additives to break down waste products or chemically alter them so that they are less harmful or more easily cleaned up. Some of these chemicals can be added directly to a contaminated site. Advantages include being suitable for field scale application. Disadvantages include cost and the potential to produce side products that are still toxic.

Physical treatments include using heat to burn or break down waste, or filtering contaminants from water or soil. This may be advantageous because some infrastructure already exists to perform physical treatments. However, these methods range in cost and are limited in the types of sites and waste that can be treated.

Bioremediation with naturally occurring microbes uses algae, bacteria, fungi, or yeast to degrade environmental pollutants leaving harmless substances like water, carbon dioxide, and organic material. Applying microbes or supplying indigenous microbes with nutrients or resources that can help them survive has been used to treat sites contaminated with petroleum products, solvents, and pesticides. This may be advantageous because there is less environmental disturbance compared to methods that require excavation. The process, however, is generally slow, limited by environmental conditions, less effective against complex pollutants, and often unable to meet the rapid cleanup demands of industrial sites or completely break down pollutants.

Source: GAO analysis of scientific literature. | GAO-26-108175

Engineered microbes are bacteria, fungi, algae, or other single-celled organisms that scientists have modified through gene editing or directed evolution (see chapter 2.1 for more information). Engineered microbes may solve challenges that conventional bioremediation cannot. For example, naturally occurring microbes are not suitable for all types of waste and contaminated environments. Some chemicals, like PFAS, contain multiple strong bonds that are difficult for microbes to break down. In these instances, engineering biology may provide solutions.

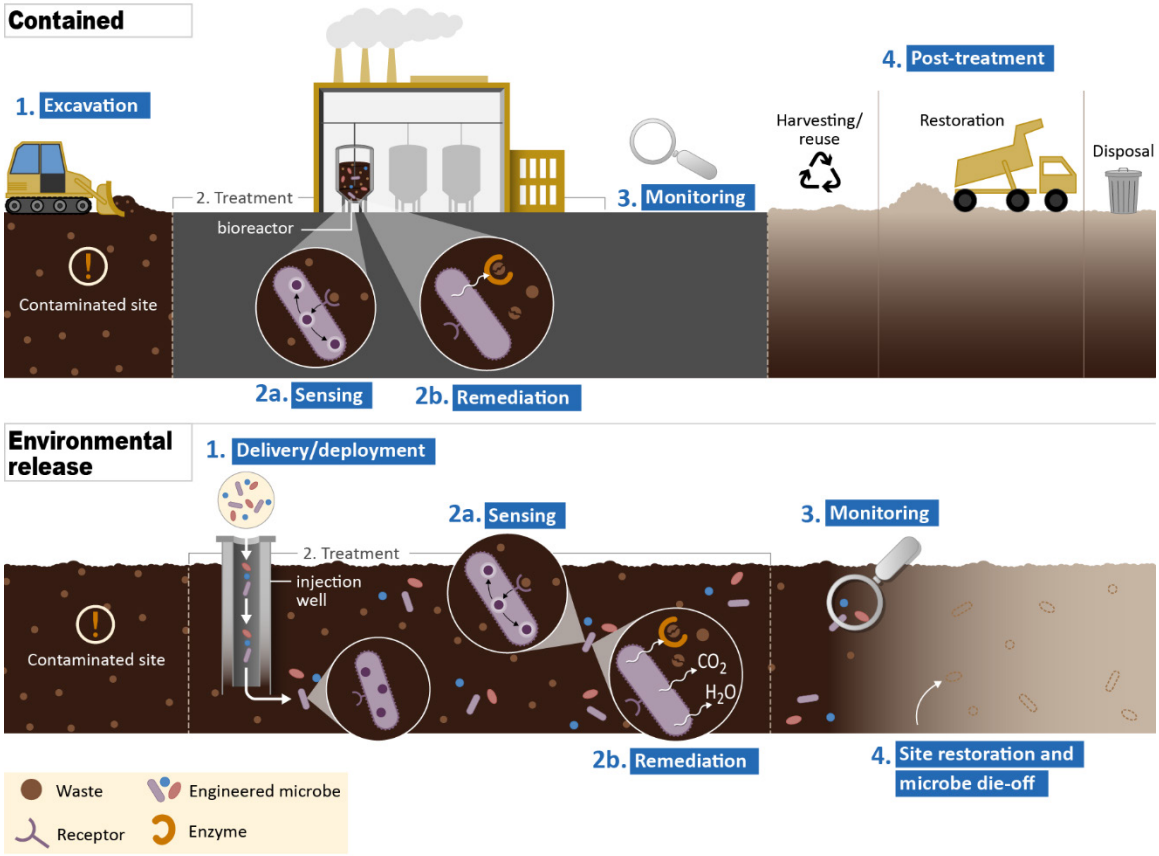
1.2 Considerations for containment versus environmental release

Bioremediation (with engineered or naturally occurring microbes) can occur in the environment where contamination is found or the contaminated material can be moved to a new location.[7] If the contaminated material (e.g., soil, water, plant matter) is moved to a new location, microbes may be used in physically contained systems or in an uncontained manner. For contained bioremediation, microbes are kept in a contained environment with the material that needs remediation. For uncontained bioremediation, microbes may be released directly into a contaminated environment or into contaminated material that has been moved out of the original location but is not physically contained. Figure 2 depicts example remediation sites using either contained or uncontained microbes.

[7]Bioremediation is the degradation or cleanup of waste or contaminants with living organisms, including plants (phytoremediation), or adding nutrients to soil to speed up degradation with microbes already present (biostimulation). This report will focus on remediation and cleanup techniques using microbes added to contaminated materials.

Treating contaminated material in place is called *in situ* bioremediation while treating material that has been moved to a new location is called *ex situ* bioremediation. While all methods of contained bioremediation involve moving contaminated material to a new location (*ex situ)*, some *ex situ* methods do not use microbes in physical containers. We make the distinction between contained and uncontained usage due to the way EPA regulations apply to genetically engineered microbes (see 1.3).

Figure 2: **Engineered microbes may be designed for contained use or environmental release**



Source: GAO. | GAO-26-108175

Uncontained bioremediation (i.e., environmental release) is usually less expensive and less labor intensive than contained bioremediation, as the contaminated materials do not need to be excavated and transported. However, with contained bioremediation, users have better control over conditions like temperature and oxygen levels, which can allow microbes to work more effectively. Contained bioremediation may also make it easier to reclaim valuable materials, such as recyclable plastics or concentrated minerals. Importantly, contained microbial bioremediation may prevent engineered or non-native microbes from entering the wider environment and interacting with the natural ecosystem.

Advances in biotechnology could allow developers to engineer and deploy microbes that complement existing cleanup methods or offer new methods to address waste. For example, some microbes can be engineered to carry out chemical reactions that their naturally occurring counterparts cannot. Experts told us that enzymes produced by engineered microbes may be the only way to break the multiple strong chemical bonds such as those found in PFAS.

1.3 Role of federal agencies

We identified key federal agencies that fund and conduct research on engineered microbes for waste cleanup or that regulate the development and use of engineered microbes (see table 1).

Table 1: Key federal agencies involved in research and regulation relevant to engineered microbes for waste cleanup

Agency	Role
National Institute of Standards and Technology	**Funding and research agency**. Leads and participates in standards development, promotes measurement science and innovations, and convenes stakeholders to accelerate research and commercialization of engineered microbes.
Department of Energy	**Funding and research agency**. The Office of Science supports fundamental research on microbial genomes, enzymes, and microbial engineering for mission relevant purposes. The Office of Environmental Management handles active cleanup of department sites.
Department of Defense	**Funding and research agency**. Uses and conducts research on microbes to remediate various contaminants at its sites.
National Science Foundation	**Funding agency**. Provides funding for basic and applied biotechnology research through grants and cooperative agreements.
National Institutes of Health	**Funding agency**. Provides funding for basic and applied biotechnology research through grants and cooperative agreements.
Environmental Protection Agency	**Regulatory and funding agency**. Responsible for regulating some microbes that are genetically engineered or designed for environmental release.
Department of Agriculture	**Regulatory and funding agency**. Responsible for regulating some scenarios in which engineered microbes are also plant pests, or contain DNA from a plant pest, and which involve importation, interstate movement, or environmental release.
Food and Drug Administration	**Regulatory agency**. Responsible for regulating biotechnology products related to food, drugs (including live biotherapeutics), and cosmetics.

Source: GAO. | GAO-26-108175

Generally, the regulatory process involves three agencies (Environmental Protection Agency [EPA], Food and Drug Administration [FDA], and Department of Agriculture [USDA]) and multiple statutes and regulations. Which agencies are responsible, and which regulations apply to a given engineered microbe, depend on a number of factors such as its genetic makeup, its geographic origin, and its intended use. For example, if genetic engineering involves introducing DNA from another genus to create a new microbe, EPA may require reporting under the Toxic Substances Control Act (TSCA), as amended.[8] If developers intend to release the microbe into the environment as part of research and development, EPA may require a TSCA Environmental Release Application (TERA) or a Microbial Commercial Activity Notice

[8]Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. § 2601 et seq.).

(MCAN).[9] USDA regulates microbes that are plant pests or contain DNA from such organisms, and which involve importation, interstate movement, or environmental release. FDA only regulates engineered microbes in limited use cases such as for food, drugs (including live biotherapeutics), and cosmetics. Key information on the regulatory process may be accessed through the Unified Website for Biotechnology Regulation.[10]

The U.S. Coordinated Framework for the Regulation of Biotechnology lays out federal regulatory policy for ensuring the safety of biotechnology products. Since 1986, the regulatory agencies (EPA, USDA, and FDA) have operated under this framework.[11] Agencies have worked to improve the framework multiple times in the last 40 years (see fig. 3). In 2022 and 2023, the three agencies conducted a stakeholder outreach process on what changes would improve the clarity and efficiency of the biotechnology regulatory process.[12] In 2023, the agencies released plain-language information on the regulatory roles and responsibilities of each agency, including case studies that show how several example products would be regulated.[13] In 2024, agencies published a plan to update and streamline regulation of biotechnology products that fall under the Coordinated Framework as biotechnology advances. However, as of March 2026, agency officials told us this plan is on hold because Executive Order 14081 was rescinded (see fig. 3).

[9]40 C.F.R. §§ 725.105 and 725.205.

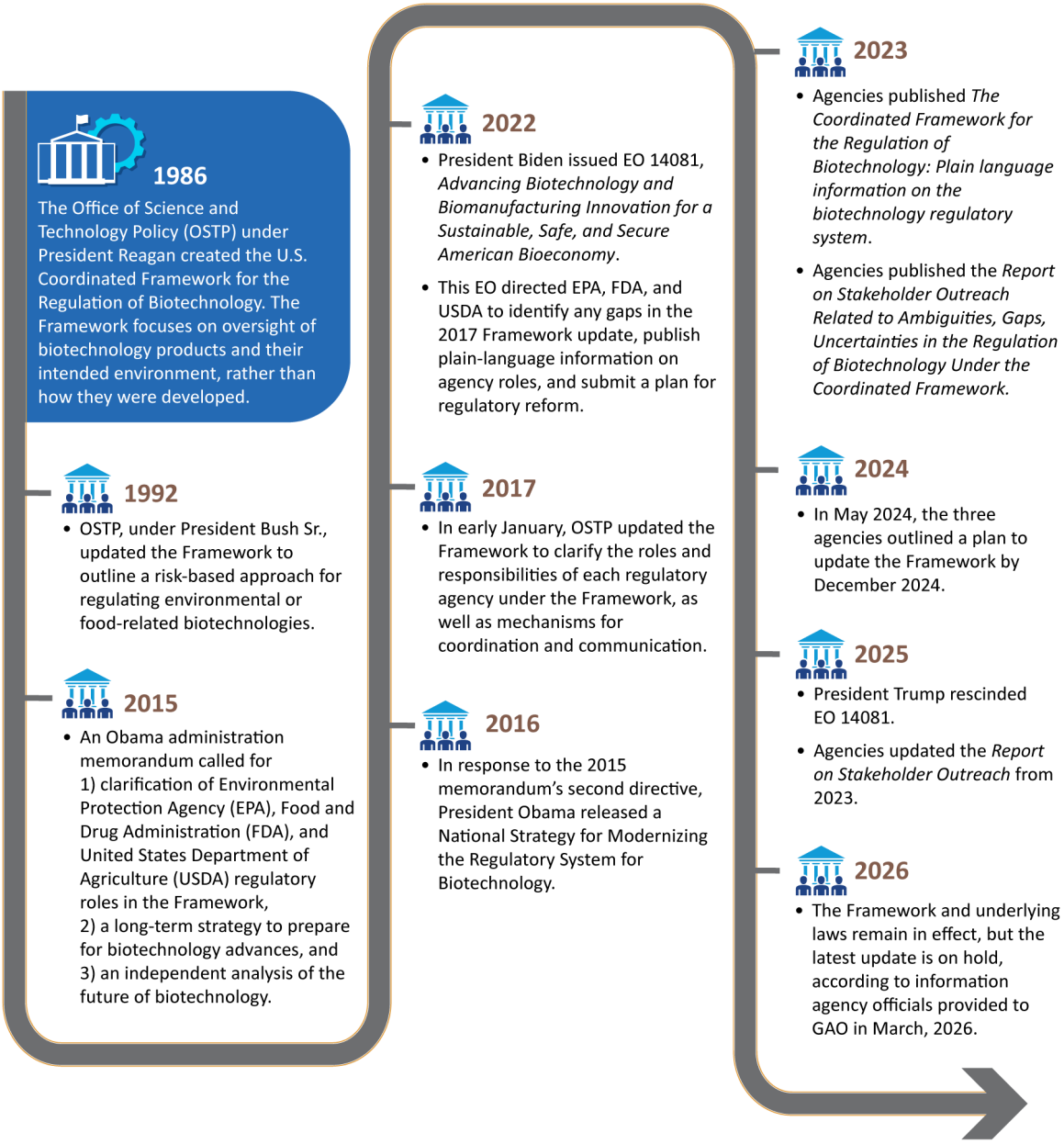
[10]The Unified Website for Biotechnology Regulation, jointly managed by EPA, FDA, and USDA, provides an interactive tool and a contact form for developers to communicate with agency officials. See: "The Unified Website for Biotechnology Regulation". https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home, accessed on Feb. 17, 2026. EPA also makes available summary and guidance documents through epa.gov that describe how to navigate its regulatory process for engineered microbes. See: EPA, Office of Pollution Prevention and Toxics, *Points to Consider When Preparing TSCA New Chemical Notifications*, OMB Control No.: 2070-0012 (June 2018); EPA, *Microbial Products of Biotechnology: Summary of Regulations under the Toxic Substances Control Act*, (September 2012); EPA, Office of Pollution Prevention and Toxics, *Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms* (Washington D.C.: June 2, 1997).

[11]According to the Unified Website for Biotechnology Regulation, "the U.S. Coordinated Framework for Biotechnology outlines a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The goal of the Coordinated Framework is to ensure public confidence in the regulatory system and improve transparency, predictability, coordination, and efficiency of the biotechnology regulatory system." See "The Unified Website for Biotechnology Regulation". https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home, accessed on Feb. 17, 2026.

[12]USDA, EPA, FDA, *Report on Stakeholder Outreach Related to Ambiguities, Gaps, Uncertainties in the Regulation of Biotechnology Under the Coordinated Framework* (March 21, 2025). Members of the developer community submitted a majority of the comments, including developer organizations of all sizes, academic researchers, and persons from outside of the United States. Stakeholders with an interest in biotechnology regulation also submitted comments to the agencies, including producer, manufacturer, and retailer groups as well as several public interest nongovernmental organizations, one of which submitted a sign-on letter from 6,083 members.

[13]USDA, EPA, FDA, *The Coordinated Framework for the Regulation of Biotechnology: Plain language information on the biotechnology regulatory system* (November, 2023).

Figure 3: History of the coordinated framework for the regulation of biotechnology



Source: GAO (analysis); GAO (top left icon); Uniconlabs/stock.adobe.com (remaining icons). | GAO-26-108175

2 Benefits, Limitations, Potential Risks, and Status of Engineered Microbes for Cleanup

2.1 Engineered microbes may offer benefits over existing remediation and waste treatment

Using engineering biology, a subset of biotechnology research, scientists can engineer microbes (or a community of microbes) that may offer several benefits over naturally occurring microbes and other conventional waste treatment methods (see text box).

Examples of engineering biology methods

Engineering biology allows scientists to change living organisms to achieve specific goals. Scientists may add or remove traits—the physical, metabolic, or behavioral characteristics controlled by genes—to allow organisms to perform certain tasks. Two examples of biological engineering methods are:

Gene editing

Gene editing encompasses several techniques for changing the genetic material of a living organism to alter its characteristics. Modern techniques like CRISPR allow researchers and developers to make precise edits in targeted sections of genes. These techniques can offer much higher control over the types of changes made to an organism and allow researchers to edit the genomes of a wide variety of species. A disadvantage of techniques like CRISPR is that researchers need preexisting knowledge of the genes that drive a function to edit them.

Directed evolution

Directed evolution is an in-lab approach that mimics natural evolution on a short time scale to change microbes or the enzymes produced by microbes. Researchers may create a large pool of microbes with mutations in their genes, then select the microbes with features they want to replicate. Because microbes reproduce quickly, this process can be repeated on successive generations until researchers create entirely new traits. This approach can be advantageous when researchers are not sure exactly which genes control the trait they want to create.

Source: GAO analysis of scientific literature. | GAO-26-108175

The potential benefits of using engineered microbes for waste treatment include the ability to tailor them to cleanup needs, improved effectiveness of natural microbes, and the potential to add value to waste.

Tailoring. Engineered microbes could be tailored to the environment, to the type of waste present, to persist for a desired length of time, and to have tracking or sensing capabilities. For example, a microbe could be engineered to sense and detoxify chemicals like TNT in the soil at a Department of Defense (DOD) test site and then die off when the TNT is completely broken down. Additionally, microbes could be tailored not just individually, but as a cooperative community where different microbes handle different stages of a cleanup process.

Effectiveness. Engineered microbes or microbial communities may also be more effective at breaking down waste than naturally occurring microbes. Individual microbes could be optimized to break down waste faster or more completely, leave behind fewer toxic byproducts, survive in harsher environments, or keep working with less expensive fertilizer or supplemental chemicals. For example, scientists could engineer microbes that degrade petrochemicals to tolerate either salt or fresh water depending on where they will be deployed to clean up oil spills. In microbial communities, toxic intermediates produced by one microbe as waste could serve as the next microbe's food source, further enhancing effectiveness.

Adding value. Engineered microbes can be designed to create or concentrate valuable products from waste. This "waste valorization" is the process of adding economic value to otherwise low-value waste products, enabling a circular economy (i.e., a system where waste is minimized by repurposing and recycling materials) and reducing the amount of waste that needs to be contained. For example, a manufacturing plant could use an engineered microbe to salvage critical minerals from electronic waste. Expanding to microbial communities, this could be modularized, meaning one microbial community breaks down the waste and another builds the high-value product.

2.2 Limitations and potential risks may restrict use or be difficult to address

2.2.1 Technical limitations

The following technical limitations, among others, restrict the use of engineered microbes for bioremediation and waste treatment. These limitations may be difficult to address through policy but could resolve with time and additional research.

Persistent chemicals are difficult to degrade. Very complex chemicals or those with strong molecular bonds may be difficult to degrade. In such cases, microbes would need to degrade the chemicals in multiple steps, or multiple species of engineered microbes could be needed to fully break the chemicals down without releasing toxic byproducts (i.e., with microbial communities). Further, as manufacturers create new types of chemicals, scientists will need to engineer new pathways to degrade them.

Widespread contamination makes cleanup challenging. Getting microbes into complex environments at the scale of a large remediation project is difficult. When contaminants are widespread, treatment requires microbes that can function well in many types of environments. They would also need to reproduce and persist long enough to ensure sufficient contact between microbes and waste to effectively break down the waste.

Fitness and competition favor naturally occurring microbes. Engineered microbes that are released into the environment would need to compete with the microbes that are already present for nutrients and other resources. These naturally occurring microbes may be better adapted to survive in the environment. These challenges may make it harder for engineered microbes to reproduce and persist long enough to complete a cleanup project.

2.2.2 Potential risks

In addition, potential risks posed by this biotechnology, while uncertain, need to be considered.

Risk of spread. According to experts from academia and government and scientific literature we reviewed, there are potential negative consequences if engineered microbes are released into the environment. For example, engineered microbes may reproduce beyond desired locations or exchange genetic information with native microbial species. However, in some cases, researchers have developed mechanisms to minimize the risk of spread. For example, microbes can be engineered to self-destruct under specific conditions or upon depletion of the target contaminant. As stated above,

natural microbes may also outcompete engineered microbes which could mitigate this risk. Additionally, the risks and associated effects of spreading engineered genetic material, if any, are not yet known because there have been so few instances of engineered microbes being released in the environment for waste cleanup to learn from.

Unknown health effects. While there is no evidence that engineered microbes pose a particular risk to human or animal health, there are concerns among some individuals about unknown effects on human or animal microbiomes.[14] For example, it is common for scientists to introduce genes for antibiotic resistance into bacteria to help them isolate bacteria that have been successfully engineered. (By exposing the bacteria to antibiotics, scientists can eliminate those that have not taken up the new genetic material.) If these microbes are later released into the environment, genes for antibiotic resistance may spread. In theory they could then spread to microbes that cause human disease. However, as a general practice, scientists carefully select and design antibiotic resistance genes to minimize the chances of this outcome, according to scientific literature. Multiple modern genetics techniques such as CRISPR may eliminate the need to include antibiotic resistance genes altogether. Additionally, engineered microbes, designed to withstand conditions in contaminated sites could be resistant to other known chemical and physical control mechanisms.

2.3 Engineered microbes for waste cleanup are not commercially available

Although technologies for engineering microbes are advanced, engineered microbes for use in remediation and waste cleanup are not. Recent advances in gene editing technologies, as well as rising concerns about widespread persistent contaminants in the environment, have spurred renewed interest in biological solutions to clean up waste. No engineered microbes for such cleanup are commercially available and there is disagreement regarding whether engineered microbes should be restricted to contained settings or released into the environment.

One avenue of development is engineering microbes for use in contained settings, such as removing certain contaminants from waste streams before the waste is released into the environment. For example, large fermenters of microbes may be used at a manufacturing facility to process wastewater that contains microplastics before it leaves the facility. This approach may avoid risks associated with releasing engineered microbes into the environment, but contained uses may not be sufficient to address pervasive and persistent contaminants that are already in the environment. It is also not possible to excavate or to have infrastructure available at every site in need of remediation.

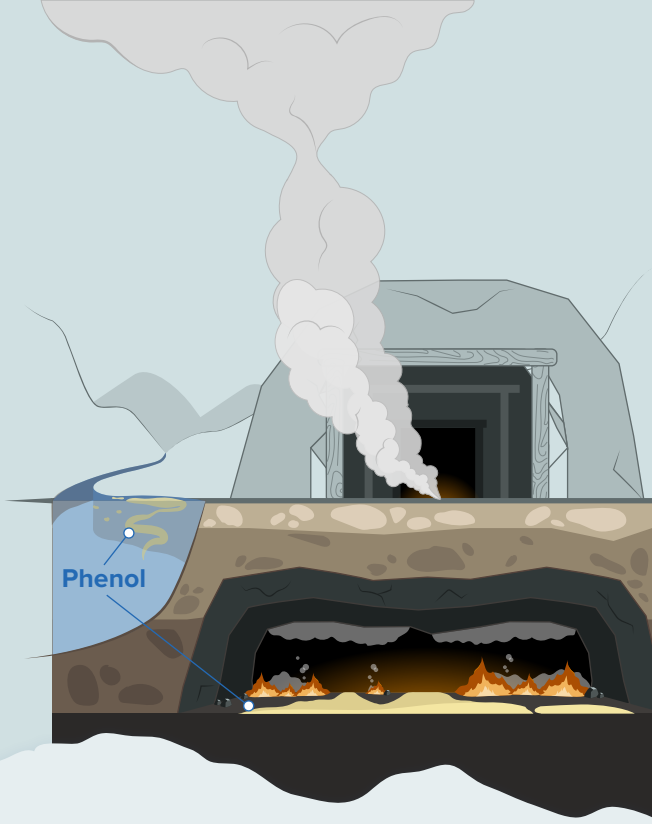
The other avenue of development is the release of engineered microbes at a contaminated site. No such microbes are available commercially, but we identified two examples of this application of the technology.

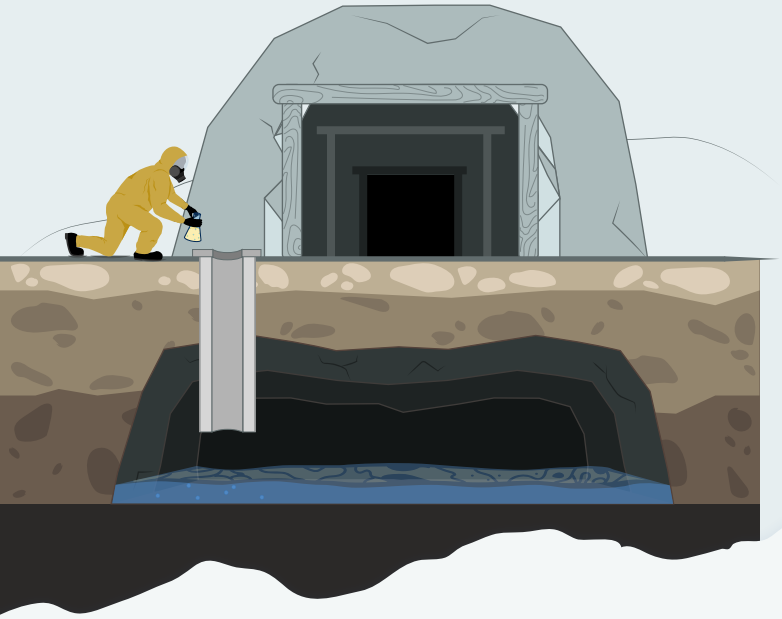
[14]The microbiome is the complete genetic content of all the microbes that typically inhabit a particular environment, especially a site on or in the body.

ESTONIA MINE CLEANUP

The Site and Contaminants

In November 1988, a large underground fire broke out in an oil shale mine in Estonia (then part of the Soviet Union). Oil shale is used for fuel or to produce crude oil, and it releases phenols when burned. Firefighters extinguished the fire, but phenols leaked out of the mine and contaminated the local river and lake. Both short-term and long-term exposure to phenols can cause health problems, including skin irritation and organ damage. It can also harm fish and other aquatic wildlife.





The Cleanup

To clean up the contaminated water, Estonian researchers introduced phenol-degrading genes into two lab-grown strains of *Pseudomonas putida*, a common soil bacterium. The researchers released the engineered microbes into a shaft of the flooded mine and, after several days, phenol levels decreased by more than half.[a]

The Follow-up

Mining activities resumed after the fire, and smaller amounts of phenol continued to be released into the river and lake. Researchers returned to the mine in 1994 to measure long-term effects of releasing engineered microbes. They found the introduced engineered genes in the genomes of native microbes.[b] In 2023, a different group of researchers told us that they also detected the engineered genes in native microbes living in areas still polluted by phenol, but they did not find any remaining engineered *Pseudomonas putida* microbes. This finding suggests that the genes introduced in the original bioremediation effort continue to be beneficial.

Source: GAO (analysis and illustrations). | GAO-26-108175

[a]E. Parakhonsky, "Underground Fires in Oil Shale Mines: Special Traits of Their Spreading, Extinguishing and Liquidating of Consequences," *Oil Shale,* vol. 12, no. 1 (1995): 63–77, https://doi.org/https://doi.org/10.3176/oil.1995.1.06.

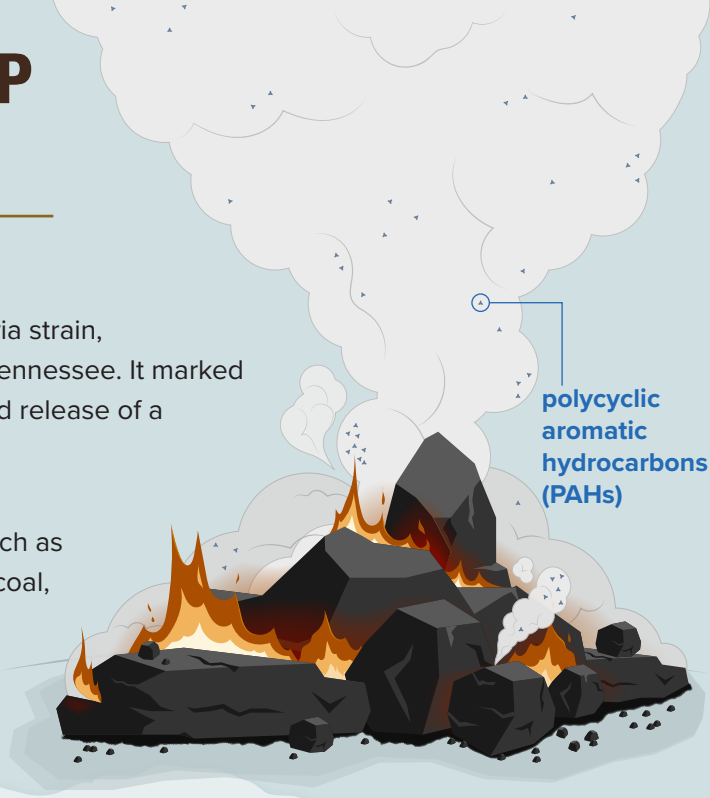
[b]M Peters et al., "Acquisition of a Deliberately Introduced Phenol Degradation Operon, pheBA, by Different Indigenous *Pseudomonas* Species," *Applied and Environmental Microbiology,* vol. 63, no. 12 (December 1997): 4899–4906, https://doi.org/10.1128/aem.63.12.4899-4906.1997.

CONTAMINATED SOIL CLEANUP IN THE UNITED STATES

The Site and Contaminants

In 1996, EPA approved a test release of a genetically engineered bacteria strain, *Pseudomonas fluorescens* HK44, at Oak Ridge National Laboratory in Tennessee. It marked the first—and according to multiple sources, currently the only—U.S. field release of a genetically engineered microbe for bioremediation.

Researchers wanted to show that HK44 could successfully survive in an ecosystem as a tool to monitor and remediate harmful contaminants, such as polycyclic aromatic hydrocarbons (PAH), which can come from burning coal, crude oil, and gasoline. PAHs can cause health problems, including cancer. PAHs can also make land unusable.



The Cleanup

To detect and break down PAHs, researchers at Oak Ridge and the University of Tennessee added genes to HK44 from microbes that had naturally evolved the ability to break down PAHs. They also introduced a gene that would cause HK44 to glow when PAH waste is present.

Researchers placed contaminated soil and HK44 into large steel structures. After the three-year test period, the levels of PAHs decreased substantially, at least partly because of HK44. But native microbes also may have contributed to this process, making it difficult to quantify how effective HK44 was. (The experiment was designed only as proof of concept.)[a]

The Follow-up

In a follow-up study 14 years later, researchers found genetic material similar to HK44's DNA, but the engineered microbes themselves had not persisted or caused any changes to the soil or native bacterial community. Researchers could not detect any PAHs in the soil.[b]

According to researchers, regulatory requirements and economic factors have prevented HK44 from being commercialized, either for monitoring or remediation.

Source: GAO (analysis and illustrations). | GAO-26-108175

[a]Steven Ripp et al., "Controlled Field Release of a Bioluminescent Genetically Engineered Microorganism for Bioremediation Process Monitoring and Control," *Environmental Science: Technology,* vol. 34, no. 5 (February 2, 2000): 846–53, https://doi.org/10.1021/es9908319.

[b]Ji, X., S. Ripp, A. Layton, G. Sayler, and J. Debruyn. "Assessing long term effects of bioremediation: soil bacterial communities 14 years after polycyclic aromatic hydrocarbon contamination and introduction of a genetically engineered microorganism," *Journal of Bioremediation and Biodegradation,* vol. 4, (October 10, 2013), https://doi.org/10.4172/2155-6199.1000148.

The above examples demonstrate the potential for engineered microbes to provide effective solutions for contamination. Through expert interviews and document reviews, GAO identified two policy goals related to this biotechnology—demonstrating safety and effectiveness and developing a market. But we also identified challenges hindering these goals. We detail these challenges, along with options that policymakers could consider if they wish to address these challenges, in the next two chapters. In chapter 5, we discuss an alternative goal if policymakers do not wish to advance the development or use of engineered microbes for waste cleanup.

3 Demonstrating Safety and Effectiveness

A demonstration of the safety and effectiveness of releasing engineered microbes is needed before advancing commercial deployment of this technology for waste cleanup. We identified three challenges that may impede such a demonstration: gaps in knowledge (3.1), insufficient testing infrastructure and standards (3.2), and regulatory burdens (3.3). In each case, we developed options that policymakers could consider to help address these challenges. The policy options are possible actions policymakers can take—which may include legislative bodies, government entities, academia, industry, and other groups.

3.1 Gaps in knowledge

Experts told us that the field needs a better understanding of which microbes may contain traits of interest, what conditions can keep them alive and active, how they interact with existing microbes in the community, and how they function to break down waste. Closing this knowledge gap may allow developers to design testing protocols and generate safety data, and allow microbes to be used for a range of cleanup scenarios.

Traits of interest. Even after decades of research, the field has knowledge gaps on which microbes exist in nature with traits that could be useful in bioremediation, according to experts. Many microbes have not been cultivated in labs and their roles in ecosystems are not fully known. Advances in gene sequencing techniques and computational studies have accelerated discovery, but experts told us that such research is underfunded. In addition, experts said that the field needs a mechanism to help prioritize the efforts that are most likely to identify useful microbial traits.

Bioprospecting

Bioprospecting is the process of searching for naturally occurring species with useful traits. Bioprospecting has led to benefits for agriculture, pharmaceutical development, and nanotechnology. For bioremediation, researchers search for microbial species with useful traits, such as tolerance for extreme environments, faster reproduction, and the ability to break down different chemicals. Researchers collect microbial species or genetic samples and bring them back to the lab to look for these traits.

Source: GAO analysis of scientific literature.| GAO-26-108175

Conditions for survival and growth. To clean up waste, engineered microbes will need to survive the local conditions and grow at rates sufficient to degrade large amounts of chemicals. But they are often less robust than naturally occurring microbes. Experts said the field needs to better understand what conditions these microbes need and to develop ways to ensure survival and growth in the desired environments.

Ecological interactions. According to experts, the field currently cannot predict how existing microbial ecosystems will respond to engineered microbes. Because engineered microbes have only been deployed at scale for waste cleanup twice (as discussed earlier), there have not been sufficient opportunities to fully study their effects on ecosystems. Better understanding these interactions would increase the chance of effective cleanup and reduce the chance of harmful effects on an ecosystem.

Function in bioremediation. Experts told us the field does not fully understand how different “functions” of microbes can most

effectively break down a specific chemical. Microbial functions can include using chemicals as energy sources, secreting enzymes to break chemicals down into less toxic forms and absorbing the resulting chemicals into the microbe. It is likely that multiple microbes and functions are needed to break down complex chemicals like PFAS. Understanding microbial function and growth is important for designing testing protocols and generating safety data to understand the risk of adverse effects. Closing this knowledge gap could allow developers to engineer and combine multiple strains of microbes for a range of cleanup scenarios.

The policy option shown in table 2 may help address gaps in knowledge.

Table 2: Policy option for gaps in knowledge

Policy option	Opportunities	Considerations
Invest in basic research, development, and demonstration projects. *Potential implementation approaches:* Congress or funding agencies could provide research and development incentives through funds or tax credits. Agencies with cleanup liabilities, such as the Department of Energy, could fund research. Private entities with cleanup liabilities or cleanup missions could fund research in this area. Companies could integrate research funding into their corporate social responsibility business approach. Key stakeholders—such as funding agencies, private companies, or universities —could increase opportunities for collaboration such as participation in conferences and working groups.	Could enable more or faster development and could provide benefits outside of bioremediation. Could more quickly close key knowledge gaps.	Will require additional resources to fund basic research, or a shift in funds away from other research areas. May require long-term research funding to enable the study of microbial survival and interactions. May place additional burdens on federal agencies that oversee research. Without structure and identified priority areas, there is risk of scattering efforts across studies that might not close the knowledge gaps. May not always be clear who has cleanup liabilities. Companies may not be inclined to spend in this manner.

Source: GAO. | GAO-26-108175

3.2 Insufficient testing infrastructure and standards

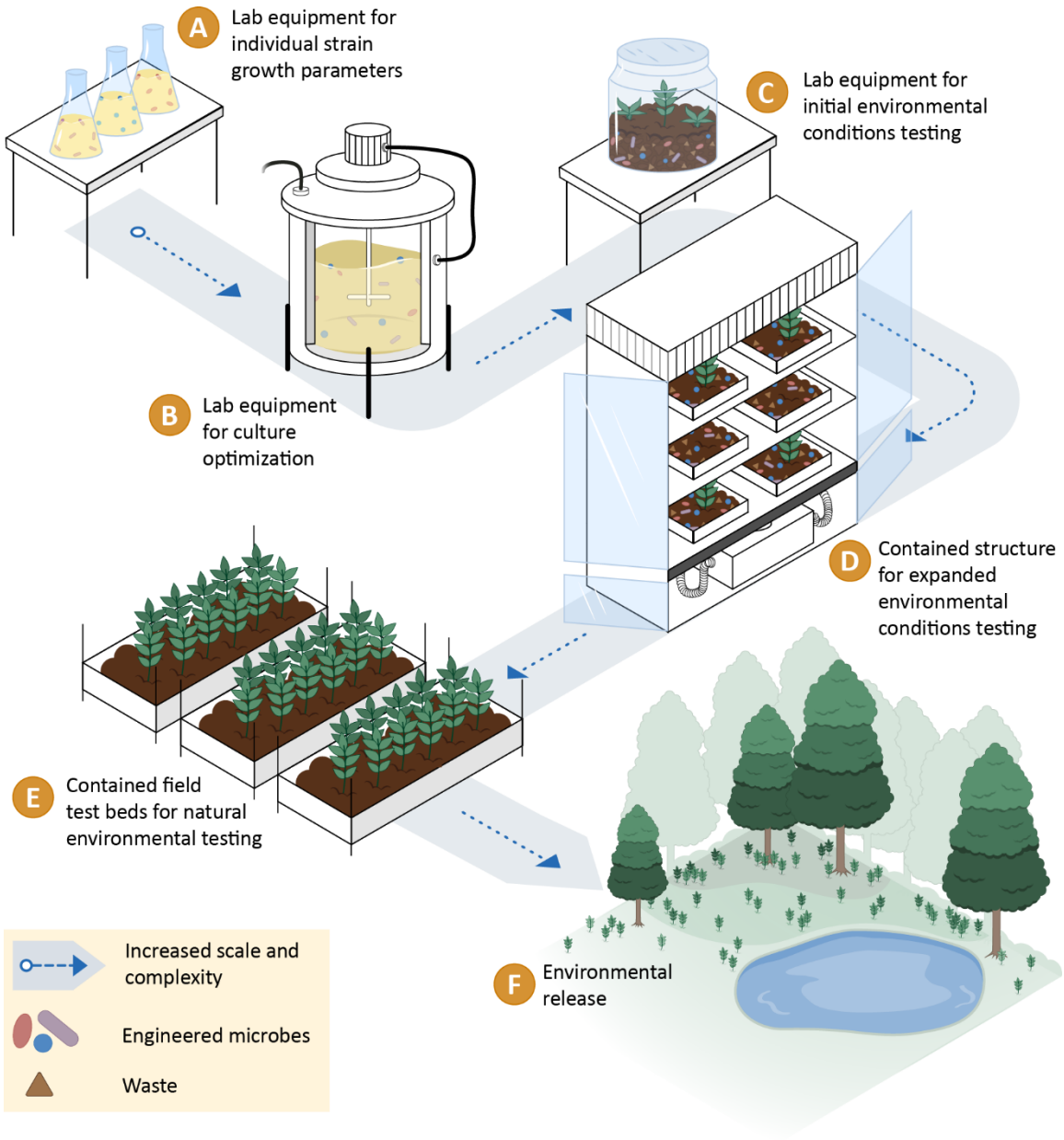
Testing is required to identify beneficial traits and to find ways to promote survival, growth, and microbial functions that break down waste (see 3.1). Once that knowledge gap is closed, further testing will be needed to develop engineered microbial products, prove that they work, and generate safety data that allow regulators to evaluate risks.

According to experts, this testing at present lacks two key forms of support—infrastructure and standards.

Testing infrastructure. Experts told us that, depending on the application, there is a general lack of testing infrastructure to scale experimentation beyond the lab and mimic real environments. Testing infrastructure could range from simple equipment to large-scale test beds, which may offer containment for engineered microbes but also attempt to mimic the conditions in environments where cleanup is needed (see fig. 4). For example, test beds may provide fluctuating temperature, humidity, sunlight, pH, and naturally occurring plants and microbes. Without sufficient testing infrastructure, experts told us that developers are not able to demonstrate safety and effectiveness of engineered microbes for bioremediation.[15]

[15]EPA requires that developers provide sufficient information for EPA to evaluate the proposed research and development activity and obtain EPA's approval prior to releasing engineered microbes into the environment for bioremediation for research and development purposes. 40 C.F.R. §§ 725.1, 725.255, and 725.260

Figure 4: Scaling up testing of engineered microbes for bioremediation



Source: GAO (analysis and illustrations). | GAO-26-108175

Standards. Experts told us that, depending on the application, the industry does not have standards for testing to demonstrate safety and effectiveness of deploying engineered microbes. Industry standards might include methods for delivering and dispersing engineered microbes or for measuring waste breakdown. Without standards, each developer would design its own testing parameters and criteria for safety and effectiveness, which would make it difficult for customers and regulators to evaluate technologies.

Standardization can help promote more rapid and effective technology development by saving developers the time needed to establish methods and criteria. Experts also said that it is important to create and define shared terminology for regulators and developers.

Experts said that the field currently lacks standards for certain aspects of testing to demonstrate safety and effectiveness partly because there is no central industrial organization to develop and publish voluntary consensus standards.[16] Sharing of methods or noncompetitive field trial data within the field could reduce testing burden on developers, according to experts.

The two policy options shown in table 3 may help address the lack of testing infrastructure and standards.

Table 3: Policy options to improve testing infrastructure and standards

Policy option	Opportunities	Considerations
Support or participate in public-private partnerships to develop testing infrastructure and standards. *Potential implementation approaches:* Congress or funding agencies could provide support to public-private partnerships that develop testing infrastructure and standards. Agencies with existing testing infrastructure or contaminated sites, such as the Department of Energy or Defense, could partner with researchers or industry to test technologies.	Could enable more or faster development of engineered microbes for bioremediation and could provide additional infrastructure. Could benefit development of other biotechnologies. Could promote collaboration across the industry to establish agreed-upon standards and methods.	Additional federal spending may shift resources away from other emerging technologies. Standards may require general consensus among multiple stakeholder groups, such as standards-coordinating bodies, developers, end users, regulators, and government agencies, which may be difficult to obtain.

[16]The National Institute of Standards and Technology (NIST) has developed a bioeconomy lexicon, which is a list of terms and definitions related to bioeconomy that was developed in consultation with an interagency working group; however, according to experts, the industry has not fully adopted it. NIST Bioeconomy Lexicon, https://www.nist.gov/bioscience/nist-bioeconomy-lexicon, accessed April 9, 2026.

Policy option	Opportunities	Considerations
Establish databases to share noncompetitive field trial data among developers. *Potential implementation approaches:* Agencies could dedicate specific resources for a database to share field trial data. Industry stakeholders could devote resources to develop shared databases.	Could decrease risk in technology development and accelerate product development. Could reduce testing burden on developers.	Efforts may be limited by developers' willingness to share proprietary data. Specific data about government owned sites may be sensitive.

Source: GAO. | GAO-26-108175

3.3 Regulatory burdens

Experts identified three areas in which the current regulatory process poses an obstacle to demonstrating safety and effectiveness of this technology.

Burdens on small-scale testing. Experts told us that the regulatory process places a heavy burden on small-scale, basic research on genetically engineered microbes for environmental release. For example, researchers are asked to provide certain information as part of the TSCA Environmental Release Application (TERA),[17] but some institutions, like universities, may not have the infrastructure to generate such information, according to experts. EPA officials told us that basic research on naturally occurring microbes for environmental release does not have any regulatory requirements under TSCA. EPA does, however, require submission of a TERA for experimental environmental release of new microbes under TSCA.[18] Experts told us that it would make sense to reduce regulatory requirements for smaller-scale studies owing to their lower risk.[19] EPA officials told us that there is no cut-off based on size of a study below which a TERA or MCAN is not required, but that the size of the study is considered in EPA's risk assessment and decision whether to approve the application or notice.

[17]EPA regulations implementing TSCA require submission of a Microbial Commercial Activity Notice (MCAN) 90 days prior to manufacturing, processing, or importing the new microbe, which EPA uses to assess, and if necessary, regulate risks. See 40 C.F.R. pt. 725, subpt. D. For research and development activities for commercial purposes, EPA allows researchers to submit a TSCA Experimental Release Application (TERA) as an exemption from the full MCAN reporting. See 40 C.F.R. pt. 725, subpt. E. The TERA must include sufficient information for EPA to conduct a reasoned evaluation of the health and environmental effects of the planned test in the environment. 40 C.F.R. §§ 725.255(a) and 725.155. If EPA determines that the proposed research and development activity does not present an unreasonable risk of injury to health or the environment, EPA will approve the TERA, allowing the applicant to proceed with the proposed activity. 40 C.F.R. § 725.270(b)(2).

[18]According to EPA guidance, a manufacturer may submit an MCAN for any research and development activity, but EPA expects that most researchers will instead choose to submit a TERA because of the longer MCAN review period and the conditions that EPA would likely impose as part of the MCAN review to address the uncertainties regarding the microbes' potential effects on human health and the environment. EPA, Office of Pollution Prevention and Toxics, *Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms* (Washington D.C.: June 2, 1997).

[19]One expert pointed to another EPA program that uses this approach as an example. Under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA does not generally require an Experimental Use Permit on field tests involving 10 acres or less.

Regulatory catch-22. Experts told us that the TERA requests information that is difficult to provide without first conducting the release. For example, EPA requests that researchers describe in the TERA how a microbe may spread before it can be released into the environment for research and development activities. According to EPA officials, EPA only requests information that is known or reasonably ascertainable and does not require conducting a release. For example, researchers may provide information from published literature or from studies that may have been conducted within a lab. But experts said that potential spread is difficult to accurately predict without testing microbes in the environment.

The TERA also requests information on how the proposed microbe will be contained. However, some engineered microbes may work best when designed for spreading and persisting and designing them with containment measures may hamper their effectiveness. For example, the two known uses of this technology for the bioremediation of waste both resulted in introduced genes being detected in the environment and that may still be breaking down the existing contamination (see vignettes on pp. 14–15).

Risk aversion. In some cases, regulatory decisions may assume a level of risk that does not align with actual environmental risk, according to experts and scientific reports. For example, whether EPA review is required depends in part on whether or not the microbe is modified using only genetic material from its own species or from a very close relative. Intergeneric modifications—those using genetic material from less closely related groupings—typically require EPA's TSCA risk review before experimental environmental release can occur. Conversely, intrageneric modifications—those using genetic material from the same species or very closely related group (i.e., genus) —generally do not trigger this review.[20] EPA officials told us they base their regulatory decisions on a thorough assessment of potential risk to human health and the environment. They believe that intergeneric microorganisms may have a significantly higher probability of exhibiting new traits or new combinations of traits compared with naturally occurring microorganisms. However, some experts have stated that this distinction may have little relevance to potential ecosystem harm. A minor intrageneric edit could theoretically create a more harmful microbe than an intergeneric change, but EPA officials told us they believe this would be a rare event. The current TSCA process incentivizes researchers to favor intrageneric traits even if they would be less safe or less effective than intergeneric traits, according to experts in the field.

[20]Researchers may source new traits in microbes from another species within the same genus (intrageneric) or from a species in a different genus (intergeneric). A genus is a category within the biological classification system. This system starts with broad categories and progressively groups organisms, such as microbes, into very specific groups of closely related organisms. The most specific categories are families (organisms with broad kinship to each other), genus (organisms that are close relatives) and species (the exact type of organism, or 'individual').

The policy option shown in table 4 could help address these regulatory challenges.

Table 4: Policy option for regulations

Policy option	Opportunities	Considerations
Update legal requirements and associated guidance documents. *Potential implementation approach:* Agencies could update regulations to reflect improvements to modern gene editing and environmental applications.	Could provide a scaled approach to regulations for small-scale research and better enable research on engineered microbes for environmental release. Updated regulations may remove the requirement to conduct a regulatory review based on intergeneric genetic changes.	Updates may not be necessary if agencies can provide better guidance or a coordinating office to help developers navigate the regulations (see table 5). Changes may add significant burden on regulatory agencies.

Source: GAO. | GAO-26-108175

4 Developing a Market

Due to the expense and scale of waste treatment and remediation, private investment may be necessary to move from innovation to deployment. But experts told us that engineered microbes for cleanup are facing multiple market failures, including limited economic consequences for producing waste, few economic incentives to address waste, and little information on a potential customer base. We identified three challenges that may discourage private investment. We also offer options that policymakers could consider to help address each challenge.

4.1 Unclear regulatory responsibilities and long review times

We identified the following two ongoing challenges within the U.S. regulatory system which may be affecting private market development.

Unclear regulatory roles and responsibilities. According to experts we spoke with and documentation we reviewed, the regulatory process for engineered microbes is unclear. It is often not clear to developers which agency is responsible for regulating a given engineered microbe and why. For example, a single microbe designed for bioremediation would likely fall under the jurisdiction of the EPA, but it could also trigger a USDA review if the microbe, or the byproducts of the remediation process, are deemed to be a risk to plants. EPA officials told us they encourage developers to contact them, but that they get very few questions regarding jurisdiction through the Unified Website for Biotechnology Regulation or directly. It is also often not clear to developers what information agencies need to make determinations. For example, EPA requests information on how long a microbe for environmental release will persist or disseminate (spread) but the agency has not set a threshold for what an acceptable life span is.

Regulatory agencies assist developers with the regulatory process, but challenges persist because there is no centralized office to help developers navigate the regulatory landscape, according to reports and experts. For example, the Unified Website for Biotechnology Regulation provides resources, an interactive tool, and a contact form for developers to communicate with agency officials. [21] However, it is not intended for regulatory submissions for product developers. One expert said that the website would be improved if it could accept a "unified review package" for all three agencies, but that meaningful regulatory change is unlikely to occur without a dedicated coordination office.

[21]The Unified Website for Biotechnology Regulation provides guidance on how to navigate the regulatory process, such as links to each agency's role and an interactive tool that provides information and resources. See: "The Unified Website for Biotechnology Regulation," https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home, accessed on February 17, 2026.

Another expert told us that the regulatory process would be more streamlined if risk assessments for biotechnology products were standardized across regulatory offices and developers could submit a single package for review with step-by-step instructions. But the expert also noted that neither the Unified Website nor a national office would fully address this challenge because different statutes require different risk assessments.

Long and unpredictable review times. Experts told us that long and unpredictable review times are a deterrent to investing in research and development for this technology. Because of limited staff at regulatory agencies and the newness of the technologies, agencies may not have the appropriate expertise in house to effectively review some proposals, leading to delays. Officials from the Defense Advanced Research Projects Agency told us they ended a project on engineered microbes for waste cleanup in part because of long review times at multiple agencies. EPA officials told us that EPA consistently completes reviews for their biotechnology program within the timeframes established in the regulations—60 days for TERAs and 90 days for MCANs.

It is also burdensome to be required to submit a new application for every new engineered microbe before experimental environmental release can occur, even for new variants or mixtures of microbes that have already been approved, according to experts in the field. The chemical industry has historically had the infrastructure, resources, and experience to meet TSCA's risk assessment requirements for new chemicals, whereas academic or small-scale developers of microbes may not. EPA officials told us that they are discussing internally and with industry representatives, options for improving EPA's biotechnology program and are looking for ways to be more efficient while maintaining an effective, risk-based approach.

The three policy options shown in table 5 could help address these challenges.

Table 5: Policy options for unclear regulatory responsibilities and long review times

Policy option	Opportunities	Considerations
Increase communication between regulators and developers. *Potential implementation approaches:* Agencies could update the Coordinated Framework for the Regulation of Biotechnology and associated guidance documents to clarify and streamline the regulatory process. Regulatory agencies could provide opportunities to advise developers on engineered microbe classifications, especially early in the development process.	Could increase the predictability of the regulatory process.	Experts continue to point to communication challenges despite recent agency efforts such as adding functionality to the Unified Website for Biotechnology Regulation.

Policy option	Opportunities	Considerations
Ensure agencies have appropriate staffing to complete timely reviews. *Potential implementation approaches:* Congress and agency leaders could ensure that regulatory agencies have the necessary staff and expertise to complete their reviews. Regulatory agencies could partner with qualified outside reviewers to review applications when they do not have in-house expertise.	Could improve the speed and predictability of the regulatory process.	In addition to staffing challenges, other resources may be needed to improve review times.[a] If qualified outside reviewers are used, maintaining the confidentiality of applicants may be a challenge. Agency officials would need to vet and manage outside reviewers, taking time away from their regular duties. Outside reviewers may have conflicts of interest.
Establish a national office for biotechnology coordination. *Potential implementation approaches:* Congress or the executive branch could establish an office to facilitate interagency coordination and help researchers and developers navigate the regulatory process.	Could serve as a first point of entry for developers of biotechnologies seeking information on how regulations apply to them. Could provide greater clarity on and assistance with navigating regulations that apply to specific biotechnology products, including engineered microbes. Could reduce burden on agencies by taking on specific functions, such as public outreach and coordination among agencies. Congressional action could provide more stability than executive action, which can be rescinded by a new administration.	Could add another step, further delaying the regulatory review process. Will require resources. Agencies may object to another entity making legal determinations about which agency has regulatory authority in a given matter. Each agency would still have to follow their individual statutory requirements. Functions of a national biotechnology office may also be accomplished through small working groups while the technology is in early development.

[a]GAO, *EPA Chemical Reviews: Workforce Planning Gaps Contribute to Missed Deadlines* GAO-23-105728 (Washington, D.C.: Feb 17, 2023. For fiscal year 2026, EPA requested a budget of about $73 million for "Toxic Substances: Chemical Risk Review and Reduction," which is about $23 million less than the fiscal year 2025 enacted operating plan—a 24 percent reduction in funding.

Source: GAO. | GAO-26-108175

4.2 Lack of manufacturing facilities and demonstrations at scale

There is a lack of facilities to scale up and manufacture engineered microbes for bioremediation, according to experts. Few manufacturing facilities are able to produce engineered microbes in the quantities needed for a large remediation project.

Without such facilities, an expert said, there is no way to demonstrate the technology at scale, and thus no way to attract investors or customers. Barriers to developing manufacturing capability include insufficient technical expertise in the necessary industrial processes, lack of testing infrastructure and agreed upon standards (see section 3.2 above), and uncertainty about regulatory approval for any resulting

products (see sections 3.3 and 4.1). Additionally, start-up costs for building or purchasing facilities are high, and companies may face long delays before seeing a profit.

The policy option shown in table 6 may help address this challenge.

Table 6: Policy option for lack of manufacturing facilities and demonstrations at scale

Policy option	Opportunities	Considerations
Invest in scale-up and manufacturing facilities. *Potential implementation approaches:* Congress or funding agencies could encourage investment in new technology through research and development grants or tax incentives. Congress or funding agencies could create low- or no-risk loan programs to support small business biotechnology development. Government agencies could support more public-private partnerships such as BioMADE that can share costs of scale-up and manufacturing facilities.[a]	Could encourage investment in new technology. May accelerate product development. May give companies opportunities to develop scalable manufacturing processes.	Additional federal spending on engineered microbes for waste cleanup may reduce resources for supporting other emerging technologies. Shared manufacturing infrastructure may be costly to build. Congress or funding agencies would need to determine which stakeholders should be responsible for operating shared facilities.

[a]BioMADE is a public-private partnership whose mission includes enabling domestic bioindustrial manufacturing at all scales and is sponsored by the Department of Defense. "BioMADE," https://www.biomade.org/about-biomade, accessed March 26, 2026.

Source: GAO. | GAO-26-108175

4.3 Public skepticism and a lack of community engagement

Information from experts and our literature search indicates that public skepticism about genetically modified organisms (a category that includes engineered crops, animals, and microbes) may limit private market interest and investment in engineered microbes for waste cleanup.

Public concerns. We heard from experts, including developers and social scientists, that without public support for engineered microbes, developers may hesitate to invest in research and development. Experts told us that public concerns include the potential for persistence in the environment, possible human health effects, and discomfort with manipulating and patenting genetic material. However, an expert told us that the public may be more comfortable with the engineering of microbes than engineering other organisms (such as plants or animals) and with using them for waste cleanup because they are not meant to enter the food supply. Further, concerns about the ongoing presence of specific contaminants or the impacts of using alternative techniques such as chemical remediation

may outweigh concerns about engineered microbes. Experts and literature we reviewed indicate that education about biotechnology and genetic engineering may improve public acceptance, but educational campaigns may not be as effective as methods that prioritize engagement.

Uncertainties with community engagement. We heard from experts that current mechanisms for gathering public opinion on waste cleanup decisions may be ineffective. For example, they told us that public comment periods are not useful for gathering community opinions on cleanup decisions. They also said that it is difficult to determine what kind of community input is needed to decide on remediation and treatment methods. That is because disagreement in the community may be related to social and demographic factors, access to education, the presence of special interest groups, or other considerations that should be weighed when making decisions. In addition, experts said it may be unclear where the responsibility lies for making decisions about remediation and waste treatment for communities. Cleanup decisions may ultimately be made by insurers or businesses, but local, municipal, and tribal governments should be involved to ensure that communities are well represented. EPA officials said that conducting community interviews and providing technical assistance to meaningfully engage in the decision-making process is part of their community involvement activities for Superfund cleanups. Effective community involvement has been shown to move cleanups forward faster when communities are appropriately engaged. However, if there is community disagreement, the time needed to solicit stakeholder input may significantly delay cleanup timelines, increase budgets, and increase the burden on entities performing cleanups, according to EPA documents we reviewed.

The two policy options shown in table 7 may help address these challenges.

Table 7: Policy options for public skepticism and a lack of community engagement

Policy option	Opportunities	Considerations
Conduct proactive information gathering with affected communities. *Potential implementation approaches:* Government or nongovernment stakeholders could conduct deliberative opinion polls and participatory technology assessments.[a] Government agencies, industry stakeholders, or advocacy groups could collaborate with local governments, Tribal Nations, and key social organizations (e.g., churches, advocacy groups, or other important local community groups) to build consensus and encourage participatory governance.	Could demonstrate public support for novel waste cleanup technologies, which may boost investor interest. Could demonstrate public aversion to using engineered microbes, which would allow resources to be directed to other efforts. Could build trust between all parties involved in cleanup efforts, which may boost enthusiasm for new technologies.	May require that communities receive education from a trusted source before engaging with participatory governance. May require substantial resources to implement. Soliciting additional input on cleanup decisions may increase the time needed to reach decisions.
Provide community education. *Potential implementation approaches:* Government or nongovernment stakeholders could provide education on the science of gene editing, the benefits of engineered microbes for cleanup, as well as the risks of continued contamination.	Could improve public literacy and understanding of new technologies, promoting informed decision making about the use of engineered microbes. Could improve public understanding of the effects of waste and contamination in the environment, which may increase interest in cleanup efforts.	May require substantial resources to implement. May not be as effective as other efforts.

[a]A deliberative opinion poll provides participants with information about an issue and time to deliberate before forming an opinion. Results are used to help understand what the whole population would think if they had a similar chance to deliberate. Participatory technology assessments use a variety of tools to engage with the public on technology policy including citizens' assemblies, citizens' juries, and consensus conferences.

Source: GAO. | GAO-26-108175

5 Alternatives to Policies Advancing Engineered Microbes for Cleanup

Another option policymakers have is to choose not to advance the use of engineered microbes for cleanup efforts. This goal may be preferable to policymakers who have concerns about the potential risks and suitability of engineered microbes for treating and remediating waste and environmental contaminants. Further, the following alternative approaches may avoid the costs and resources associated with incentivizing private investment in this technology. However, these options may result in some challenges remaining unresolved, and certain types of waste and contaminants remaining in the environment.

5.1 Contained approaches may address some, but not all concerns about testing for environmental release

Developers may be able to address some of the challenges described above through designing engineered microbes for contained uses rather than environmental release. Using engineered microbes in physically contained systems does not require the same regulatory approvals as releasing them into the environment. Such systems might therefore be more appealing to developers and potential users.

Physically contained systems may be useful in industrial settings to treat waste before it enters the environment or minimize waste that needs to be stored or sequestered. For example, for industrial processes that produce wastewater that cannot be safely released into the environment or that contain potentially valuable products, it may be desirable to treat the water before it exits the factory. However, this approach would not mitigate contamination that is already present in the environment. Physically contained remediation projects would have to transport and store contaminated soil or water in containers with engineered microbes, which could increase the associated costs or logistical difficulties. Therefore, this approach would be impractical for many types of widespread contamination.

5.2 The private market may address some, but not all challenges

Some challenges with the private market for waste cleanup may resolve without additional intervention. For example, without additional policy actions, microbes engineered to create valuable products from waste may become commercially viable. Adding value to waste that would otherwise be worthless may be enough to incentivize private development and reduce the amount of waste that needs disposal or treatment. Microbial products that recycle plastic waste into new material and that concentrate valuable minerals from mining waste are currently under development. However, engineered microbes cannot recycle all types of waste into valuable materials. Some market challenges may therefore remain unresolved without policy intervention.

5.3 Alternative policy options

The three policy options shown in table 8 offer alternatives to advancing engineered microbes for waste cleanup.

Table 8: Alternative policy options

Policy option	Opportunities	Considerations
Maintain the status quo *Potential implementation approach:* Government agencies, industry stakeholders, and advocacy groups could maintain the status quo for funding and resource allocation.	Alternative approaches, including bioremediation with naturally occurring microbes or treatment with physical or chemical methods, may continue to be used and improved upon. Engineered microbes may be developed to treat some types of waste in contained systems. Engineered microbes may be developed to create valuable products from some types of waste. Would minimize the need for additional resources and additional burdens on regulatory agencies.	High financial, logistical, or technological barriers may persist for treating some contaminants, such as PFAS. Contaminants already in the environment may remain untreated. Market failures may continue to prevent developers' investment in certain cleanup methods or projects.
Develop policies and manufacturing practices that reduce waste production. *Potential implementation approaches:* Congress or federal agencies could enact regulations regarding waste production. Federal agencies or private companies could direct resources to engineering industrial processes to produce less waste and rely on recycled materials.	Reducing the amount of waste produced by industrial or consumer practices would decrease the resources needed to dispose of, safely store, or repurpose waste.	Would require substantial additional agency resources to enforce regulatory actions. Reducing waste production would not address waste or contaminants that are already present.
Reduce current efforts toward developing engineered microbes for cleanup.	Avoids the known and unknown risks associated with uncontained testing and environmental release of engineered microbes. Could allow resources, either financial or operational, to be reallocated to other efforts.	Would not address challenges associated with current remediation technologies, including high cost, logistical difficulty, and inability to treat all types of waste in all environments.

Source: GAO. | GAO-26-108175

6 Agency and Expert Comments

We provided a draft of this product to DOD, the Department of Energy, EPA, the Department of Health and Human Services, NIST, the National Science Foundation, and USDA.

NIST, the National Science Foundation, and USDA concurred without comment. The other agencies and some experts who participated in our work provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional addressees, the relevant federal agencies, and other interested parties. This report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact Sarah Harvey at HarveyS@gao.gov. Contact points for our Offices of Congressional Relations and Media Relations may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

//SIGNED//

Sarah Harvey
Director,
Science, Technology Assessment, and Analytics

Appendix I: Objectives, Scope, and Methodology

Objectives

We prepared this report at the initiative of the Comptroller General, to assist Congress with its oversight responsibilities, in light of broad congressional interest and the potential high value of engineered microbes. We examined (1) the status, benefits, and risks of developing engineered microbes for use in waste cleanup; (2) the challenges of developing or using engineered microbes for waste cleanup; and (3) options policymakers could consider to achieve various goals related to this biotechnology.

Scope and methodology

To address all three of our objectives, we assessed engineered microbes that may be used for waste cleanup and remediation. For all of our objectives, we reviewed peer-reviewed scientific literature and other documents describing current and developing technologies and interviewed federal agency officials and 25 other experts from government, academia, industry, and nonprofit organizations. We also reviewed federal agency guidance on the development and deployment of relevant technologies, such as the U.S. Coordinated Framework for Biotechnology that outlines a comprehensive regulatory policy for the Environmental Protection Agency (EPA), Department of Agriculture (USDA), and Food and Drug Administration (FDA). We provide more details on these methodologies below.

Limitations to scope

The list of key technologies discussed in this report is not intended to be exhaustive. Based on our review of the literature and discussions with federal agency officials and other experts, we selected technologies currently in use or under development by researchers to enable waste cleanup and remediation. Though these technologies may be developed or used internationally, the policy options we identified represent possible actions U.S. policymakers and stakeholders could take.

Literature search

To gain insight into engineered microbe applications, potential benefits, challenges, and considerations, we conducted a literature search, and reviewed federal agency guidance and other documents. We conducted scientific searches using search terms that included, “genetically modified microbe + bioremediation,” “genetically modified microbe + waste,” “genetically modified microbe + plastic,” “genetically modified microbe + heavy metal,” “genetically modified microbe + petrochemical,” “genetically modified microbe + environmental remediation” to identify relevant scientific literature.

For the scientific literature review, we considered articles that were published from 2020 to 2025 and excluded articles that were not relevant to our objectives or were published in languages other than English. We identified additional relevant articles through snowball methods, either through articles from the initial literature search or recommendations from our interviews.

Interviews and discussion groups

We interviewed federal agency officials as well as nonfederal experts with a diverse set of perspectives on the science and application of these technologies. The federal officials included individuals from EPA, USDA, the Department of Commerce's National Institute of Standards and Technology (NIST), the U.S. Department of Energy, the Department of Defense (DOD), and the National Science Foundation. The Department of Health and Human Services opted to provide written responses from FDA and the National Institutes of Health in lieu of an interview.

We also interviewed 25 experts from technology companies, universities, research institutes, government research laboratories, nonprofits, and public-private partnerships. We identified potential experts to interview through literature and document reviews, interviews (snowball approach), agency officials, and conference proceedings. We selected experts based on their expertise in at least one area related to our objectives, such as technical expertise in microbial engineering or policy expertise related to regulating engineered microbes. We interviewed these experts to establish a base understanding of engineered microbe technologies that are either available or in development and to obtain their views on the potential benefits, risks, and challenges associated with their development and use. To obtain an understanding of the key challenges identified in our initial interviews, we also convened three small groups of seven to nine of these experts to engage in a cross-sectoral discussion on technical, regulatory, social, and economic challenges. A total of 14 experts participated in these discussion groups. The 25 experts who participated in our review are listed in Appendix II.

In addition to evaluating experts on the basis of their expertise, we evaluated them for any conflicts of interest. A conflict of interest was considered to be any current financial or other interest as disclosed by individual experts, such as an organizational position, that might conflict with the service of an individual because it could (1) impair objectivity or (2) create an unfair competitive advantage for any person or organization. Of the 15 experts who participated in the cross-sectoral discussions, some were affiliated with companies, government agencies, universities, or nonprofit organizations. We took these affiliations into consideration as potential conflicts of interest when conducting our analysis and preparing our report. We determined that these experts' affiliations were unlikely to bias our overall reporting.

Policy options

Based on our research, we derived three policy goals—outcomes that could be achieved by resolving key challenges or minimizing potential risks of engineered microbes for waste cleanup. To develop these goals, we compiled a list of challenges, risks, and benefits associated with the development or use of the technology from our evidence collection and grouped them into themes.

We then analyzed the information we collected to identify potential policy options and implementation approaches that could help address the challenges within each policy goal.

Policy options are intended to represent possible actions policymakers can take to achieve a policy goal. These are not listed in any particular order, nor are they inclusive of all possible policy options. We consider policymakers to include Congress, federal agencies, state and local governments, academia, and industry. For each policy option, we discussed potential opportunities and considerations. We limited policy options to those that fit the objective and fell within the report scope.

To develop our policy options, we compiled a list of possible options over the course of our work based on review of the literature, interviews with government officials, and other experts. We further refined and assessed these options to ensure they were adequately supported by the evidence we collected, could be feasibly implemented, and fit into the overall scope of our work. We then analyzed the information we collected to identify potential opportunities and considerations of implementing each policy option. We shared the policy options with the experts using a standardized feedback form to gather any additional feedback on the options we developed.

While we identify instances where legislation may be needed to act on a policy option, we did not conduct work to assess how effective the options may be and express no view regarding the full extent to which legal changes would be needed to implement them. The policy options and analyses were supported by documentary and testimonial evidence.

We conducted our work from February 2025 to June 2026 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to technology assessments. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations to our work. Consistent with our quality assurance framework, we provided the relevant agencies and experts with a draft of our report and solicited their feedback, which we incorporated as appropriate. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

Appendix II: Expert Participation

To conduct our work, we identified experts from national labs, technology companies, universities, and research institutes that conduct research, development, or policy work related to biotechnology and engineered microbes. We selected these 25 experts based on their expertise in at least one area related to our objectives. The experts who participated in these discussions are listed below. Some of these experts provided additional assistance by sending material for our review or reviewing our draft report for accuracy.

Emily Aurand

Engineering Biology Research Consortium

Duane Blackburn

MITRE Corporation

Anastasia Bodnar

National Security Commission on Emerging Biotechnology

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Pacific Northwest National Laboratory

Drew Endy

Stanford University

Bob Friedman

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U.S. Air Force Civil Engineer Center

Kate Kucharzyk

Battelle

Keith Matthews

Matthews Law LLC

Josh Michener

Oak Ridge National Laboratory

Timothy Miller

BlueHalo

Richard Murray

California Institute of Technology

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Larisa Rudenko

BioPolicy Solutions, LLC

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Defense Advanced Research Projects Agency

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Michael Smanski

BioMADE and the University of Minnesota

Sean Simpson

LanzaTech

Kent Sorenson

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Appendix III: GAO Contacts and Staff Acknowledgments

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Staff acknowledgments

In addition to the contact named above, the following STAA staff made key contributions to this report:

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These staff also contributed to this work:

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