Genetically Engineered Soil Microbes:

Risks and Concerns

Acknowledgements

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About Friends of the Earth

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Executive Summary

A handful of healthy soil contains more microorganisms than there are people on the planet. These tiny creatures, such as bacteria and fungi, play a massive role in agriculture, making nutrients in the soil available to crops and providing crops greater immunity to pests and diseases. They are also major engines of soil carbon sequestration — a function which gives them a significant role in the soil's potential to help mitigate climate change, conserve water resources, and be resilient to droughts and floods.

Soil microbiomes are marked by incredible complexity that we are only beginning to understand. Of the billions of species of microbes that make up the living soil, only a few hundred thousand, far less than one percent, have been scientifically characterized in detail.[1]

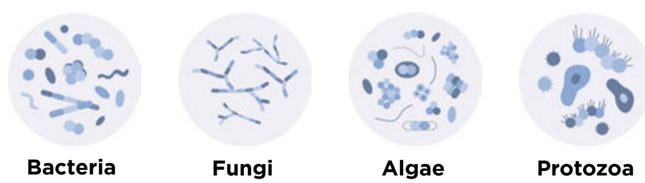
Despite these unknowns, biotech companies are developing genetically engineered (GE) microbes for use in agriculture, including the largest agrichemical corporations — Bayer-Monsanto, Syngenta, and BASF. Among the envisioned applications are engineering microbes to act as pesticides and fertilizers. The first of these products are already being used across millions of acres of U.S. farmland.

At least two live GE microbes are currently being used by U.S. farmers — a nitrogen-fixing GE bacteria from Pivot Bio called Proven® and BASF's '2.0' version of its Poncho®/VOTiVO® seed treatment, which combines a GE microbe that aims to improve plant health with a neonicotinoid insecticide and a non-GE microbial nematicide. According to Pivot Bio, their Proven® product was used on 3 million acres of corn in the U.S. by 2022.[2] The Environmental Protection Agency's website states that it has registered eight GE microbes as pesticides.[3] However, the regulatory system is marked by such a profound lack of transparency that there is no publicly available information on what they are and whether they have been commercialized.

The release of live GE microbes directly onto millions of acres of farmland is a new chapter in agricultural biotechnology — GE microbes are live organisms that can reproduce and interact with other species. Adoption of GE microbes in agriculture represents an unprecedented open-air genetic experiment. The scale of release is far larger, and the odds of containment are far smaller, than for GE crops. Consider the following: just under 3 trillion corn plants are grown each year in the United States, most of which are genetically engineered. An application of GE bacteria releases the same number of modified organisms about every *half an acre*. It is therefore essential to understand the potential risks of releasing genetically engineered microbes into the environment and to take their unique features into account when setting regulations.

This report provides historical context for this novel technology, insight into future trends, a summary of potential risks, and policy recommendations that would ensure robust assessment and oversight as more GE microbes move from the lab to the field.

Figure 1: Soil microorganisms

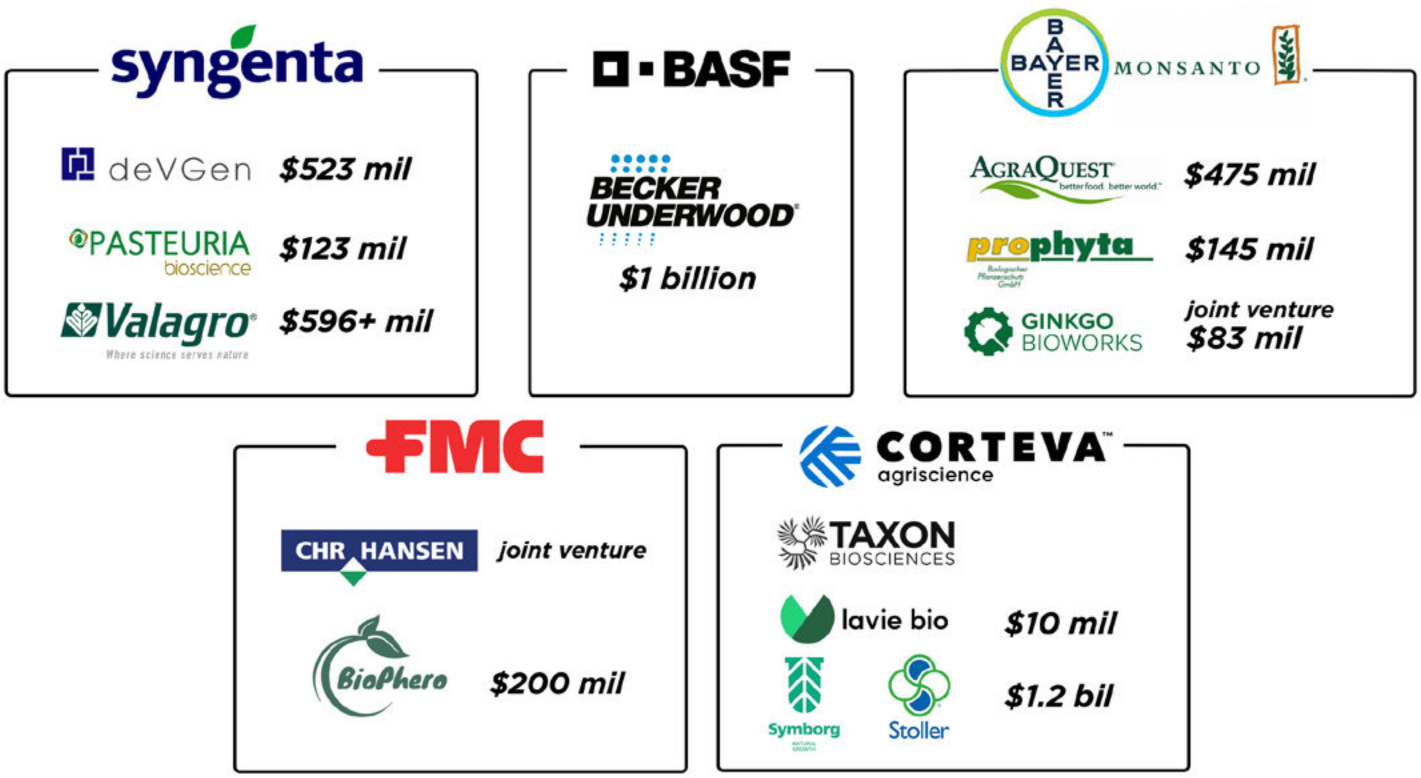


The booming 'biologicals' market and the role of agrichemical corporations

Genetic engineering is not needed to harness the power of microbes. Hundreds of naturally-derived microbes — known as 'biologicals' — are available for use in agriculture already, as biostimulants to improve plant growth, biofertilizers to improve crop nutrition, and biopesticides to manage pests and diseases. And billions of unexplored microbes exist that can be a source of discovery and benefit for generations to come without the use of genetic engineering.

The global biologicals market is expected to nearly triple in a span of eight years, from $10.25 billion in 2021 to $29.31 billion by 2029.[4] A major driver of the changing landscape is the entry of the largest agrichemical companies — Bayer, Syngenta (ChemChina), Corteva (Dow-Dupont) and BASF.

Figure 2: Consolidation in the biologicals industry, 2012-2023



These companies have spent millions acquiring biologicals companies in recent years and now offer a range of biological products.

Biologicals may be able to play a significant role in helping farmers transition to ecologically regenerative and resilient systems. At the same time, the entry of massive agrichemical companies into the field, and their interest in genetically engineering microbes, raises critical questions about whether GE microbes will be used in a way that further entrenches industrial approaches to agriculture and unjust relationships of power within the food system or whether they have any potential to become part of ecological farming systems.

The creation and distribution of genetically engineered crops has infamously been controlled by these same corporations, which have a long track record of disregarding the massive environmental and human health impacts of their products, disenfranchising family-scale farmers, obfuscating the truth about their products, and obstructing regulations.[5]

Interrogating biotech corporations' marketing claims

While a shift toward biological solutions could be a huge win for the environment and public health, farmers, policymakers, and the public will be challenged to decipher legitimate claims from false marketing. Already, Bayer and other companies are using the debunked trope of 'feeding the world' in their marketing of biologicals.

Agrichemical companies are also citing their investment in biologicals as evidence of their leadership in 'regenerative agriculture' — a movement focused on improving soil health to sequester carbon, restore biodiversity, conserve water and improve farmers' resilience in the face of climate change. Yet, they are primarily selling biologicals as part of 'integrated' platforms, such that they cannot be obtained separately from their engineered seeds, pesticides, and other proprietary products widely associated with significant harm to soil life and other biodiversity.

BASF's addition of a GE bacteria aimed at enhancing plant health to its neonicotinoid seed treatment won't solve the underlying problem of depleted soils created by the very industrial, monoculture corn and soy production in which the seed treatment is being applied — a system the agrichemical industry perpetuates and profits from. RISKS & CONCERNS

Limits of our knowledge & unintended consequences

The gaps in our knowledge and limitations of our ability to predict or control the outcomes of this novel technology are profound and varied. Genetic engineering (including gene editing techniques like CRISPR which are often claimed to be more 'precise') can result in an array of unintended genetic mishaps, including insertions, deletions, inversions and translocations that were not expected.[6] When we attempt to intentionally alter the microbiome there is no guarantee that the outcomes will be what we intend. Widely distributing GE microbes could enable new associations to form with weed or pest species with unforeseen and potentially irreparable consequences.

Ecological concerns

Lack of containment

The sheer number of GE organisms released will be orders of magnitude larger than our current experiences with GE crops, and the complete containment of microbes — which can cross national boundaries on an air current — is impossible.

Horizontal gene transfer

Unlike plants and animals, microbes are able to share genetic material with each other far more readily, even across completely unrelated organisms in a process known as horizontal gene transfer. As a result, the genetic modifications released inside GE microbes may move across species boundaries in unpredictable ways.

Altering microbial communities

While not all microbial treatments in agriculture change the existing soil microbiome, research shows that the effect can sometimes be long term.[7] Changes to the microbiome can result in changes to plant growth and insect communities — and these may be different from the intended effects.[8,9] If an agriculturally applied microbe becomes permanently established as an invasive species in the wild it could present a serious concern due to the ways it may then influence other relationships and even the structure of whole ecosystems.

Action needed – A moratorium on "guided biotics"

While there are reasons to be concerned about unintended horizontal gene transfer, developers such as Folium Bioscience are also exploring 'guided biotics' technology that intentionally increases the horizontal transfer of transgenes. In essence, this constitutes an organism that indiscriminately genetically engineers other organisms. This system shares properties with gene drives, which have been treated with far more trepidation than other types of genetic engineering. Like gene drives, a moratorium should be placed on release of 'guided biotics' systems.

Pest resistance

As with chemical pesticides, pest resistance is a critical concern for microbes engineered to express pesticidal qualities. If we are driven to adopt pesticidal GE microbes in response to the chemical pesticide treadmill, we should not assume new technology will produce better outcomes unless we learn the lessons of the past.

Human health concerns

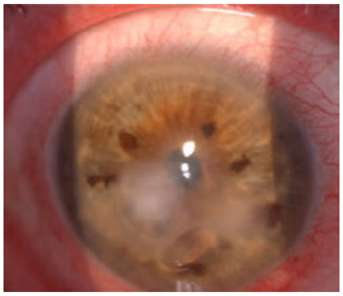


Figure 3: A human eye infected with *Beauveria bassiana*

Beauveria bassiana, is an agriculturally beneficial fungus. The patient was a 76-year-old farmer with a number of underlying conditions.

Novel pathogens

In some cases, GE microbes could become human or animal pathogens. Opportunistic infections occur from microbes that are not normally considered pathogens when certain conditions are met — such as encountering immunocompromised individuals or co-infection with specific other microbes (see Figure 3). The soil microbiome is a known source of some of these pathogens, including members of genera that are targeted for use in ag biotech, such as *Pseudomonas*, and *Ochrobactrum*.[10]

New risks for immunocompromised people

Given that the present trend in GE microbe development involves co-integration with chemicals, the real-world scenario of application includes a potentially grim intersection of factors. Multiple pesticides have immunosuppressive effects on wildlife, livestock, and humans near farms.[11] Thus, people living where GE microbes would likely be released may be even more susceptible to novel infections.

Antibiotic resistance

Antibiotic resistance markers are commonly used in the development of transgenic organisms. The use of antibiotic markers in GE microbes that might directly become human pathogens adds to the health risks. For example, the patient's infection in Figure 3 was susceptible to only two of nine tested antibiotics. Had the infection been caused by a GE fungus expressing an antibiotic resistance marker, the outcome of the case may have been affected.

Consumer exposure and the human microbiome

It should be assumed that while most microbial treatments are designed to be transient and die off while crops are still in the field, some amount of engineered bacteria will come into contact with consumers via the food supply. The overall risks of these live microbes causing health problems is very low. However, it raises potential concerns for impacts on the human microbiome.

Socioeconomic concerns

Since the commercial release of genetically engineered microbes in agriculture is so new, we don't yet know how companies' intellectual property rights to these products might impact farmers and other stakeholders in the food system. However, the history of agrichemical corporations' use of intellectual property rights to GE crops to pursue predatory lawsuits against hundreds of small farmers should raise red flags.[12] The high likelihood of genetic drift poses a threat to organic farming systems, which by law prohibit the use of GE organisms. Another socioeconomic concern is the way the growing consolidation in the agricultural biologicals market may narrow the scope of innovation in this sphere, further entrenching the economic interests of powerful corporations over the public good.

U.S. POLICY CONTEXT

The current regulatory system for GE microbes is inadequate and outdated and is marked by an extreme lack of transparency. Companies are able to redact almost all details from public view in most regulatory filings under the self-designation of 'Confidential Business Information.' Even these redacted records are difficult to access and not clearly identified with the end products in which the microbes appear. Once products are released, there is no program dedicated to surveilling the extent of their use or re-evaluating their safety over time.

The U.S. Department of Agriculture and U.S. Environmental Protection Agency (EPA) have jurisdiction over different types of GE microbes, enhancing confusion, and neither has developed regulations that take into account the unique properties and risks of GE microbes. For example, the EPA governs them under the Toxic Substances Control Act, a regulation developed for chemical pesticides, not living organisms that can replicate and trade genetic material with other organisms.

Given the serious potential risks associated with mass environmental release of GE microbes, it is imperative that civil society, farmers, and concerned scientists push for strong regulations and independent review and assessment of potential health and environmental risks. GE microbes should be regulated as novel GE organisms using process-based and precautionary assessments and oversight. Finally, a far greater level of transparency is fundamental to our ability to grapple — as a society — with the potential risks of this novel technology.

POLICY RECOMMENDATIONS

1: Recognize that genetically engineered agricultural microbes are novel

GE microbes do not fit neatly into past experience with genetic engineering. Unlike GE microbes used in industrial processes, they are not contained. Unlike GE crops, they include species that have only recently become known to science. GE microbes are unlikely to be contained and cannot be thoroughly tracked except by advanced laboratory methods combined with systematic environmental sampling of public and private land.

2: Distinguish genetic engineering from biologicals in general

GE microbes are a small fraction of microbial applications in agriculture. There is no general requirement to use genetic engineering for microbes to be useful, and some microbial technologies are ancient and grounded in traditional agricultural knowledge. Genetically engineered microbes should be evaluated in a way that assesses the specific contribution of genetic engineering.

3: Define genetically engineered microbes inclusively

In the realm of GE crops, there is a history of exemptions for certain types of genetic engineering, such as gene editing. Even if the reasons given for these exemptions are accepted, they do not apply equally to microbes. Microbes engage in a wide array of genetic functions that are not found in plants and animals. Legalistic exemptions based on whether the outcome of genetic engineering could conceivably be 'natural' should not be permitted. Any microbe that has been subjected to direct manipulation of its DNA should be subject to regulatory review.

4: Initiate a rulemaking on field trials vs. contained testing

The EPA and any other potential regulators should initiate a rulemaking on the extent to which field trials of GE microbes constitute an irrevocable environmental release. In acknowledging that full containment is unlikely to impossible, agencies should develop protocols for rigorous monitoring of the spread and effects of GE microbes.

5: Prevent containment failure from being used as a weapon of economic coercion

The tendency of GE crops to escape their fields and show up elsewhere is nothing compared to microbes that can cross national boundaries on an air current. Acceptance of these technologies should factor in acknowledgement that full containment is essentially impossible. Developers and users of GE microbes must not allow escaped self-replicating microbes to harm others' crops or, worse, to force adoption of the technology.

6. Place a moratorium on any field testing of 'guided biotics' applications

Guided biotics refers to the development of GE microbes that are *intended* to propagate and transmit engineered DNA — organisms that indiscriminately genetically engineer other organisms. This system shares properties with gene drives, which have been treated with much more trepidation than other types of genetic engineering, and should be subject to similar concern.

7: Require greater transparency

Lack of transparency on the part of federal regulatory agencies is an overarching, urgent problem for how we evaluate and oversee products of biotechnology, including GE microbes. Far greater transparency is fundamental to our ability to grapple, as a society, with the potential risks and benefits of this novel technology.

8: Use a precautionary approach

Regulatory bodies should use the Precautionary Principle to guide action, meaning that precautionary measures to minimize or avoid threats to human health or the environment should be taken based on the weight of the available scientific evidence rather than waiting for full scientific certainty about cause and effect, which can take years or decades while harm accrues. The Precautionary Principle also elevates the importance of a full evaluation of safer approaches before moving ahead with a potentially risky new technology. Oversight should include independent assessment for public health and environmental safety, and long-term impacts should be assessed before products are released onto the market or into the environment. The Precautionary Principle also guides the incorporation of public input into decision-making processes, as the impacts of new technologies such as GE microbes in agriculture will be borne by society as a whole. In addition, socioeconomic concerns arising from the expansion of corporate property rights over microbes must be incorporated into decision-making before products are commercialized.

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