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Microbial Consortia for Environmental Release: Regulatory Gaps and Potential Paths Forward

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Primary Research Questions

What scientific knowledge do regulators need to better assess microbial consortia products?

What changes in policy, regulations, and law could help bring microbial products to market?

To answer these questions: analysis of guest lectures, semi-structured interviews with 44 subject-matter experts, and literature review

Microbial Consortia and Their Impacts

Microbial consortium

An assemblage of two or more microbial populations that interact with one another such that the assemblage can carry out functions that monocultures cannot achieve.

Found in virtually every ecosystem

Function examples:

Support plant growth and diversity

Maintain the digestive systems of animals

Main drivers of primary production in oceans

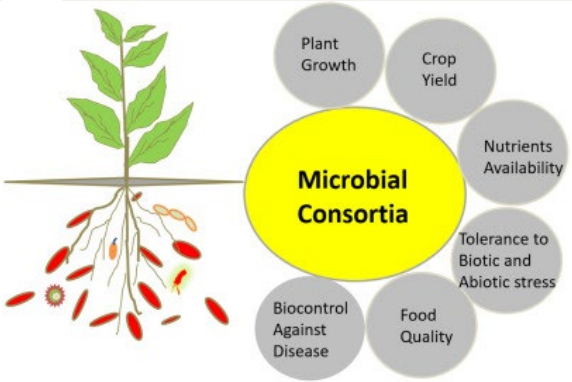
Characteristics of consortia

Tend to be more stable in response to perturbations

Frequent horizontal gene transfer (HGT)

Emergent properties arise from complex interactions

Toxin production resulting from competition



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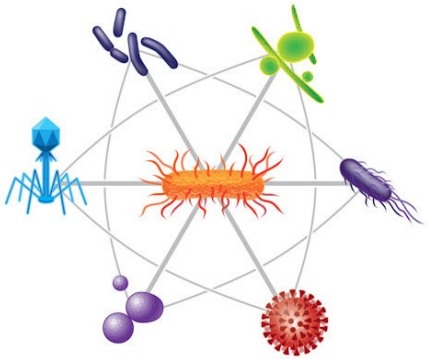
State of the Field



ASM

Product Categories

MCER - Microbial consortia for environmental release

EMCER - Engineered microbial consortia for environmental release

EMER - Fit into the larger category of engineered microbes for environmental release

Biotechnology products composed of microbial consortia are becoming more prevalent

- Though few, if any, EMCER have been approved for commercial use
- Most composed of unedited microbes selected from the deployment environment

Some potentially impactful E/MCER products may never take off because they may not be economically viable

- May only require a one-time application for long-term benefit
- Difficulty of navigating the regulatory process >> product design that can provide an ROI without much regulatory oversight
- Difficult to engineer

Environmental Release Applications of E/MCER

Environmental release applications:

Agriculture

Coral restoration and resilience

Biomining/bioleaching

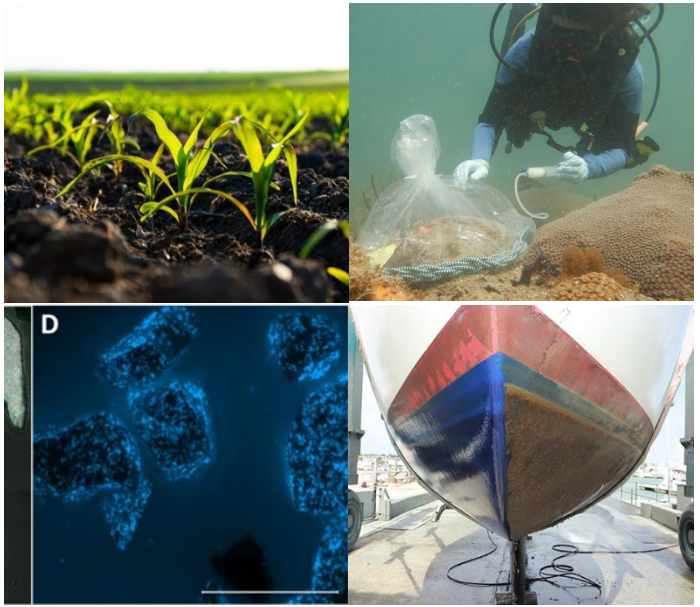
Antifouling

Forest regrowth

Wastewater treatment

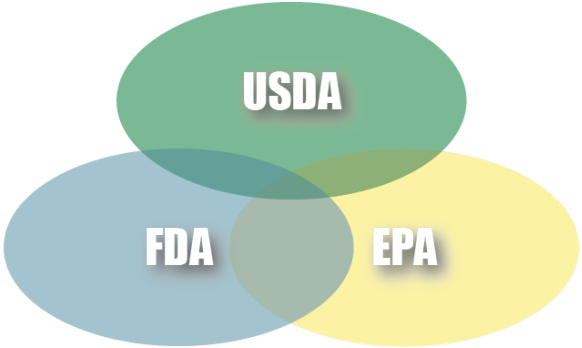
Bioremediation (of toxic substances or plastics)

Reduction of livestock methane emissions



Regulations: Built for One Organism at a Time, Usually Contained

- U.S. regulates by product & intended use — the Coordinated Framework (1986, upd. 2017)
- Built on assumptions: the unit of analysis is a single organism, contained
  - E/MCERs break this assumption
- On a moving backdrop: Overturn Chevron Deference (*Loper Bright)* · NEPA contraction (*Seven Counties*) · SECURE vacatur

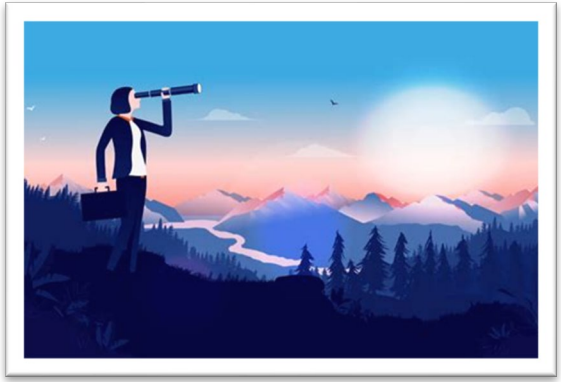


Mapping the Current Regulatory Landscape

- Landscape is broader than the three core agencies (EPA · USDA · FDA)
  - ~10 federal statutes and related rules; patchwork via states
    - Endangered Species Act (ESA)

- Traced where consortia products might land in the current regulatory process
  - Real products: PROVEN®40, Zequanox®, Fecal Microbiota Transplants, AquAdvantage®, KB-1®
  - Hypothetical consortia

- Beyond jurisdictional discussion: Methods
  - Risk analysis
  - Ecosystem services as a proxy for economic value



Challenge Areas

Seven challenge areas emerged from our analysis of guest lectures, SME interviews, and review of technical, policy, and legal literature.

For each challenge: developed a **"menu of actions“** – a list of recommendations for **agency staff, White House staff, and Congress** to choose from.

Organize around **three cross-cutting themes.**

Science & Measurement

1. Measurement standards and benchmarks for microbial consortia

Structure & Governance

2. Regulatory jurisdiction overlap
3. Microbe-specific regulatory processes
4. Capacity and legal authority to consider environmental benefits and costs
5. Flexible governance

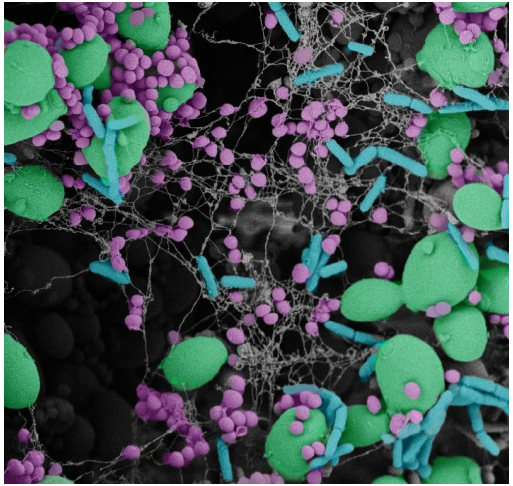
Institutional Capacity

6. Regulatory science infrastructure
7. Workforce and capacity constraints

Challenge 1:
Measurement Standards for Microbial Consortia

- While USDA and EPA policies for EMERs do exist
  - Neither agency has produced intra-agency guidance on E/MCER and their unique challenges

- Genera and species distinctions used for macroorganisms are not as definitive for microbes
  - EPA OPPT = intergeneric trigger
  - USDA APHIS BRS = list of plant pests + trigger of plant pest DNA
  - Do not necessarily capture how individual strains will behave



Brogan Richards, Univ of Nottingham

Challenge 1: Measurement Standards
Recommendation Options

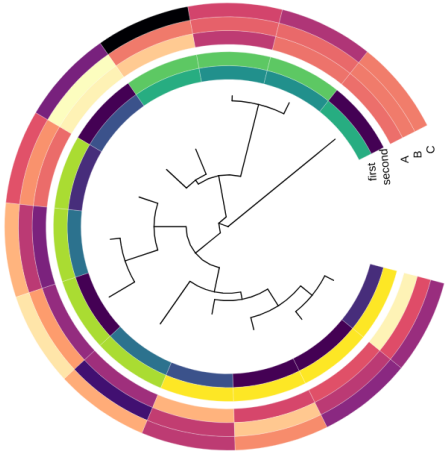
A. Establish standards for measurement techniques and accepted data types.

B. Develop large data sets to calibrate persistent or long-duration environmental deployments.

C. Develop standardized tools and methods to measure persistence and community dynamics.

D. Build more nuance into the initial screening of genetic edits.

E. Make lists of regulated microbes more flexible and accessible.



NIST
National Institute of Standards and Technology

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Challenge 2:
Regulatory Jurisdiction Overlap

- Structural mismatch: authorities are overlapping and non-overlapping at once
- Several may attach to one product, yet no single agency's scope captures the community
    - One coral intervention: up to 14 federal, state, and international jurisdictions
- Developers report needing predictability and a centralized entry point
- “Lead agency” might be a logical fallacy: agencies answer to their own statutory authorities, individual agency mandates don’t dissolve
- **Represent a technical problem as much as a people-centric one**

Challenge 2: Regulatory Jurisdiction Overlap
Recommendation Options

A. Resolve jurisdictional ambiguity through umbrella MOUs and an expanded Coordinated Framework.

B. Build and sustain communities of practice.

C. Strengthen interagency and cross-cutting guidance for microbial products.

US Army Corps of Engineers

DARPA

NOAA

NIH National Institutes of Health

NSF

U.S. Fish & Wildlife Service

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Challenge 3: Microbe-Specific Regulatory Processes

There are no clear regulatory analogs to use as a baseline for E/MCER

- USDA APHIS—focus on plants does not translate clearly to microbes
- EPA OPPT—categorization of microbes not on the TSCA inventory as “new chemicals” does not always fit
- FDA CBER—recent approvals of fecal microbiota transplant may be helpful, but the endpoint to evaluate is much clearer

The agencies recognize that the boxes don’t always fit

- USDA does not have a deregulation process for microbes, like they do for plants
- EPA OPPT has a biotechnology program within the New Chemicals Division specifically for biotechnology evaluation

Challenge 3: Microbe-Specific Regulatory Processes *Recommendation Options*

Both agencies could consider developing staged review processes, similar to clinical trials, that include checkpoints with specific criteria

- USDA and EPA could follow a similar model for E/MCER products
    - endpoint for the product is clearly defined and evaluated with respect to safety
    - Each product goes through a staged process
        - data requirements and expected outcomes clearly defined

Challenge 4:
Capacity and Legal Authority to Consider Environmental Benefits and Costs

- Framework that weighs the risk of action but not the cost of no-action may systematically undercount the value of intervention
- Ecological benefit lacks a meaningful role in the current system
  - Environmental systems are shared: a consortium enters the commons
- Healthy-baseline assumption fails in degraded systems Immaterial for most products; decisive for E/MCERs
- Where benefit is permitted, it's narrow economics: e.g., avoided crop loss

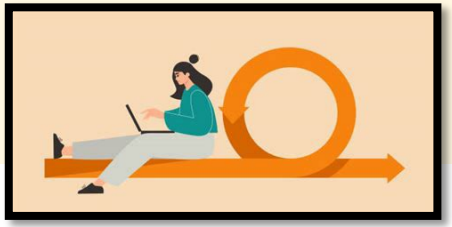
Challenge 4: Capacity and Legal Authority to Consider Environmental Benefits and Costs
Recommendation Options

A. Develop ecological endpoint and ecosystem services data standards.

B. Seek congressional authority for benefit-inclusive review where appropriate.

C. Create a designated pathway for public-interest E/MCER products.

Challenge 5: Flexible Governance



- E/MCER-class products will tend to stress two core capacities:
  - Structural flexibility: Agencies may lack (or perceive they lack) statutory room as science evolves; coupled with decreased deference
  - Feedback mechanisms: internal and external, that signal when a decision or rule needs revisiting are underdeveloped
- Few off-ramps for well-characterized products
  - Some processes exist (e.g., exemptions and rulemaking), but creating and updating these processes can be truly prohibitive
- Opportunity cost: agencies may be unable to focus resources on novel products, or areas that need it most

Challenge 5: Flexible Governance
Recommendation Options

A. Develop iterative approval pathways and bake adaptive management provisions into approval structures.

B. Seek explicit congressional authority for flexible governance mechanisms.

C. Expand external accountability and evaluation infrastructure.

Challenge 6:
Regulatory Science Infrastructure

- Inconsistent research infrastructure to make results available to/usable by regulators
- R&D outputs lack data standards
    - Industry-funded research are not readily accessible
    - The research enterprise itself is diffuse
- Limited availability of field sites
- Environmental monitoring is rarely funded long enough to capture ecological processes over years

Challenge 6: Regulatory Science Infrastructure
Recommendation Options

A. Fund and expand regulatory R&D within regulatory agencies and basic research institutions.

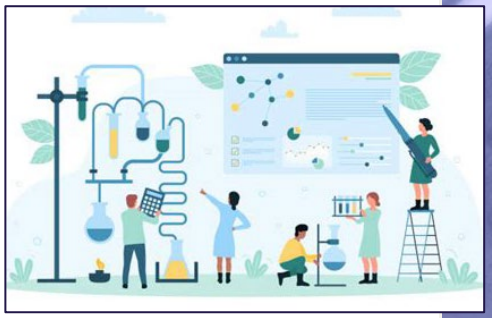
B. Build out field and laboratory infrastructure through public-private partnerships.

C. Look to international and institutional partners to help fill knowledge gaps and develop decisions support tools.

IISD

Challenge 7:
Workforce and Capacity Constraints

- Robust workforce is prerequisite for nearly every recommendation
- Well-staffed agencies are foundational to efficient, effective governing
- Agency staffs are small compared to mandated scope of the agencies.
- Capacity is uneven: Scientific, technical, and legal capacity differs across agencies
- Consortia widen the gap: E/MCER products sit in novel territory
  - Need interdisciplinary expertise in microbial ecology, community dynamics, environmental modeling, and law



Challenge 7: Workforce and Capacity Constraints
Recommendation Options

A. Staff and resource the efforts this report identifies.

B. Build matched expertise through permanent and rotational staffing.

C. Address General Counsel (GC) capacity and technical literacy.

Summary

Microbial consortia (E/MCER) products are an emerging technology that show great promise for environmental applications

The regulatory framework surrounding E/MCER products may lead developers to design around regulations, instead of designing the most impactful product

We have identified challenges E/MCER products face and proposed policy options to address each. Broadly:

- Understanding the unique biology of E/MCER in the environment requires support for further research and tailored review
- Policy changes will need to occur across federal & state governments, industry, and universities – including multi-agency reviews
- Building infrastructure and workforce capacity

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Discussion & Questions