NATIONAL ACADEMIES Sciences Engineering Medicine

Enabling Data Governance and Public Infrastructure for Engineered Microorganisms for Environmental Release

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Biotechnology Regulatory Fellowship Program

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A Roadmap for Enabling Data Governance & Public Infrastructure for Engineered Microorganisms for Environmental Release

Engineered microorganisms for environmental release are an emerging class of biotechnologies that require **fit-for-purpose data governance**.

- What are the critical knowledge gaps in their assessment?
- What are the impediments to data governance implementation?
- How can data governance enable regulatory learning?

Biotechnology regulation emphasizes contained products with discrete endpoints

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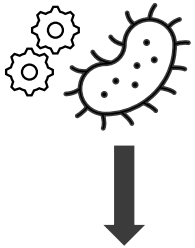
Traditional Biotechnologies



1. Design the biotechnology

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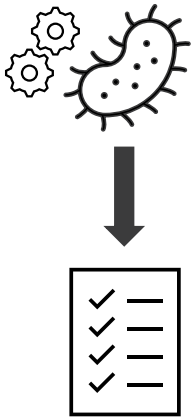

1. Design the biotechnology

2. Evaluate for safety & efficacy

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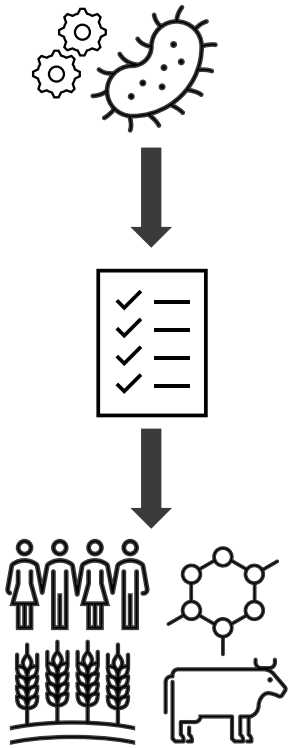

1. Design the biotechnology

2. Evaluate for safety & efficacy

3. Products enter the market

Emerging environmental crises require emerging biotechnology solutions

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Biotechnologies beyond conventional containment can provide solutions to many of these environmental crises…

…but may require integrating into and/or reshaping environments indefinitely

Many emerging biotechnologies challenge existing paradigms

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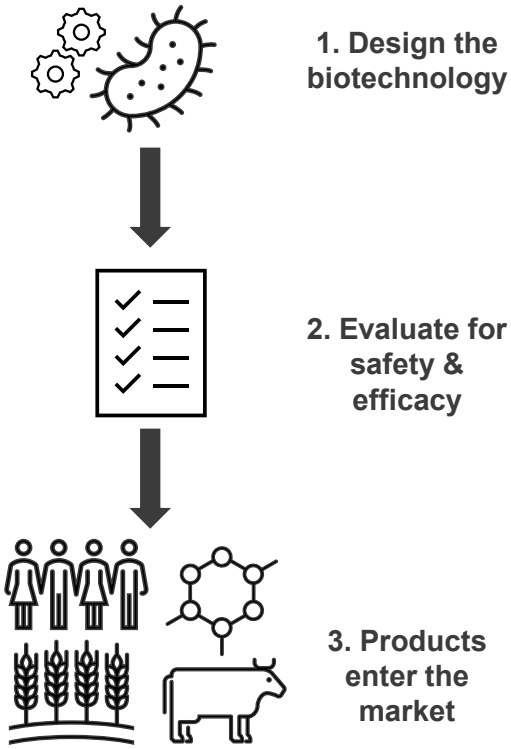
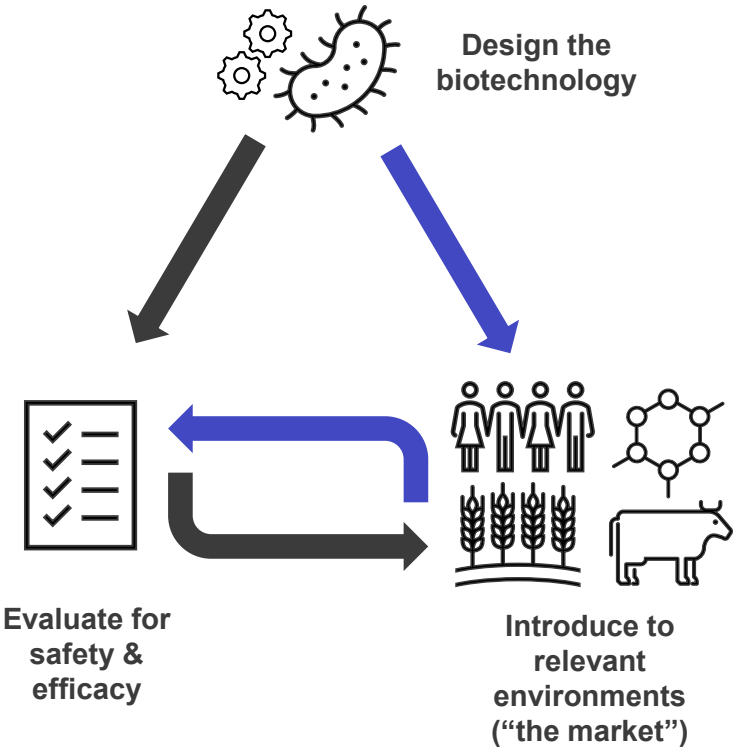


Biotechnologies Beyond Conventional Containment (BBCCs)



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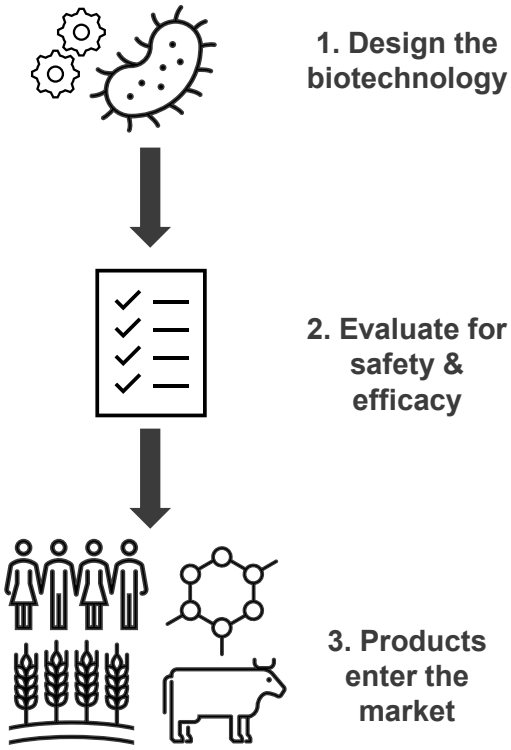
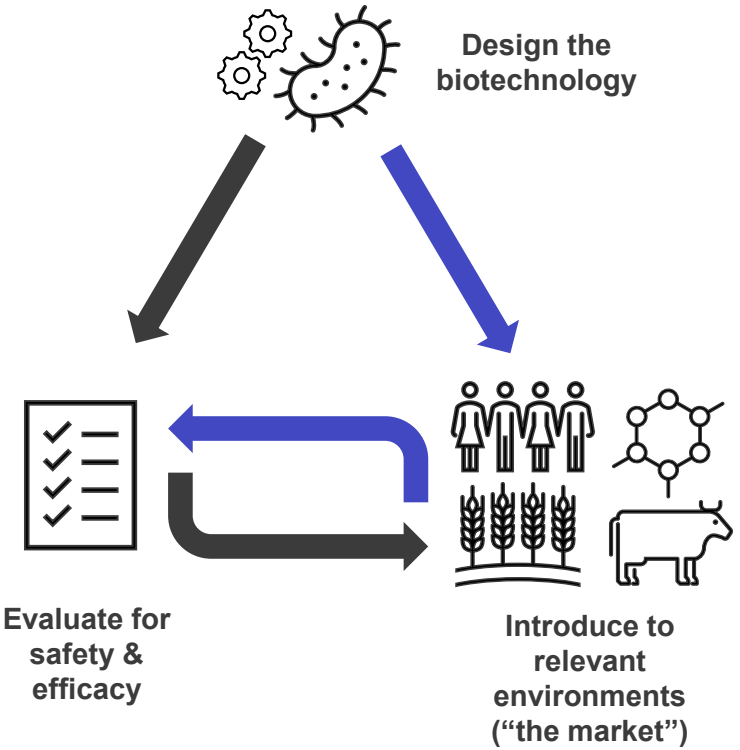


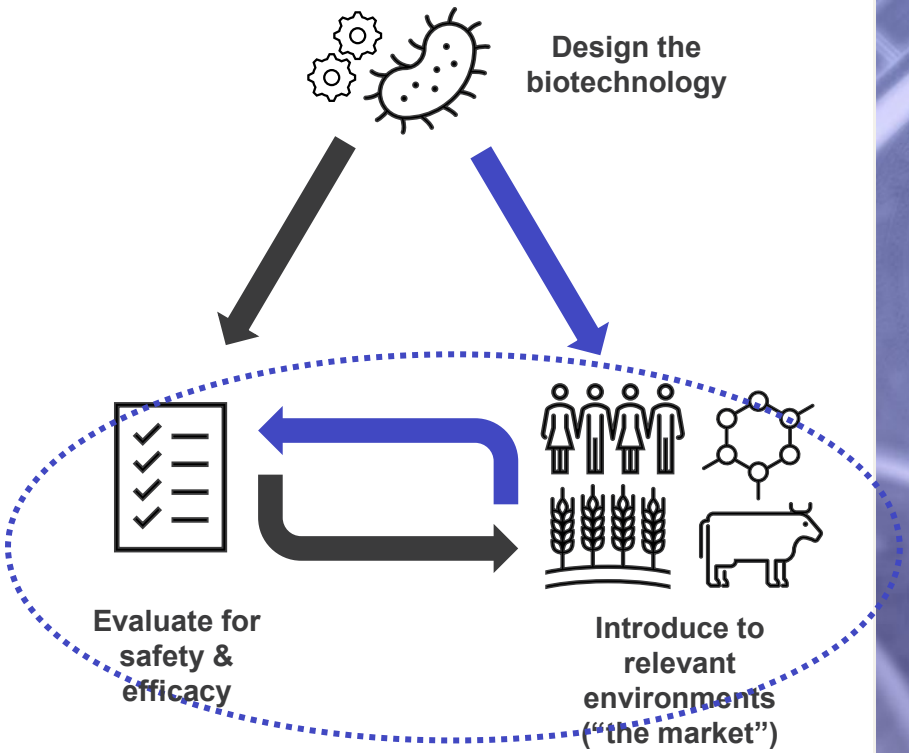
Engineered Microorganisms for Environmental Release (EMERs)



Many emerging biotechnologies challenge existing paradigms

- Safety and efficacy of EMERs is challenging to assess in laboratory settings
- Release is both a necessity and primary risk factor in their function and evaluation
- Data gaps related to:
  - Environmental persistence and spread of microorganisms and associated products
  - Gene flow and capacity for transfer of engineered genetic material
  - Ecological baselines
  - Efficacy of biocontainment strategies

Engineered Microorganisms for Environmental Release (EMERs)



Early EMER field trials led to data generation

- 1980s –engineered *P. syringae* to prevent ice crystal nucleation
- First EMER field trials, regulated under EPA-FIFRA

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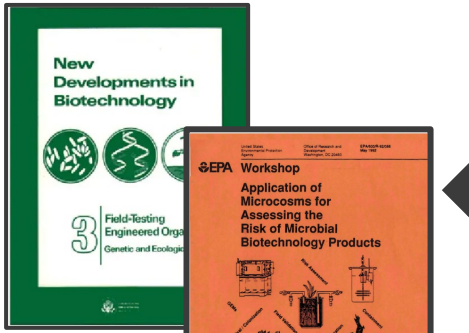

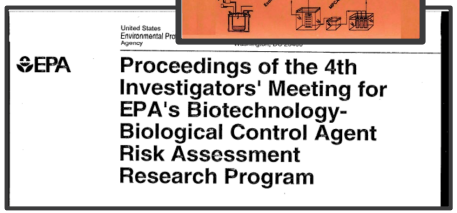

- EPA convened workshops & put out documents identifying data gaps

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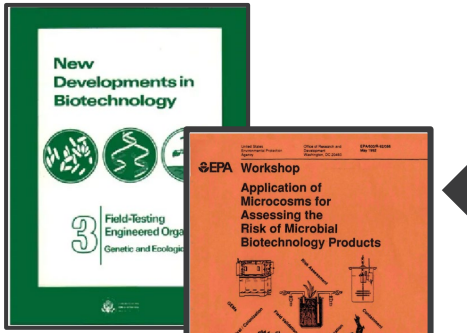
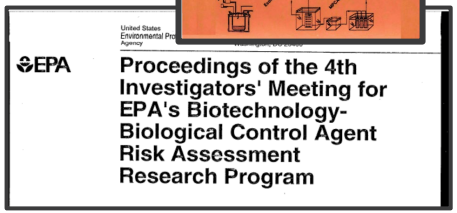
Early EMER field trials led to data generation…and controversy





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- Public controversy around GMOs
- Litigation & vandalism stalled field trials

Effective data governance can balance public good with public backlash

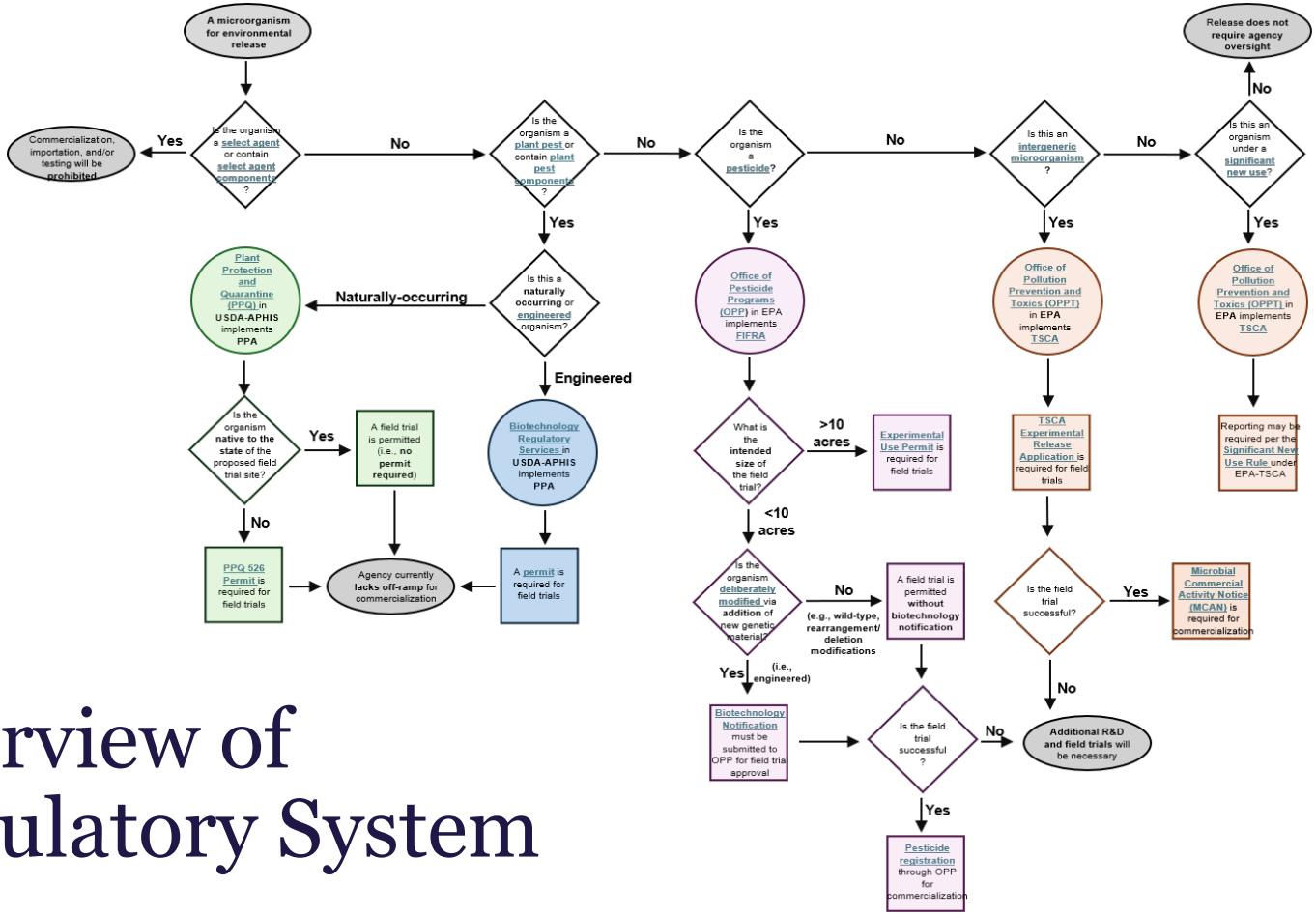
Data governance for biotechnologies include the policies, standards, and institutions that determine *what data are collected, how they are shared, who can access them, and how they inform decisions*

Effective data governance:

- ✓ Enables risk-proportionate safety assessments
- ✓ Informs on regulatory decisions
- ✓ Fosters public trust

Ineffective data governance:

- ❑ New biotechnologies start from scratch
- ❑ Design, evaluation, and implementation is not supported by foundational knowledge
- ❑ Redundancy and duplicated efforts without added benefit



Overview of Regulatory System

Agency jurisdiction is determined by regulatory trigger, with differing or overlapping data categories for field trial permits

USDA BRS regulates microorganisms that are plant pests or have plant pest components	EPA regulates microorganisms with pesticidal properties	EPA regulates all other intergeneric microorganisms
Permit	Biotechnology Notification/ Experimental Use Permit	TSCA Experimental Release Application (TERA)
✱	↓	↓
Commercialization/ Deregulation	Registration	Microbial Commercial Activity Notice (MCAN)

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USDA BRS regulates microorganisms that are plant pests or have plant pest components

- **PPA 7 CFR Part 340**
- Organism identity
- Description of genetic elements
- Anticipated or intended phenotype
- Release site
  - size, land area, map & GPS coordinates, land use history
- Experimental procedures for confinement of microbe to release site and dissemination prevention
- Termination and field devitalization
- Application Procedures
- In-trial & post-trial monitoring protocols

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- **FIFRA 7 CFR Part 158 Subpart V**
- Data categories for Biotechnology Notification
  - Organism identity
  - Host range & potential for gene transfer/ exchange
  - Natural habit of wild-type strain
  - Environmental competitiveness
  - Application procedures
  - Pest organisms involved
  - Information on genetic construct
  - Statement of composition
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EPA regulates all other intergeneric microorganisms

- **TSCA 40 CFR Part 725**
- Data categories for field trial permit (TERA/MCAN):
  - Microorganism identity
  - Information on genetic construct
  - Phenotypic and ecological characteristics
  - Health and environmental effects
  - Characteristics of test site
  - Target organisms (if applicable)
  - Byproducts of manufacturing, processing (MCAN)
  - Worker exposure and environmental release (MCAN)

Challenges in implementation of meaningful data governance for EMERs

Environmental biotechnologies require post-market evaluation

- Many assumptions of the Coordinated Framework do not map to EMERs
- Pre-market review requires uncertainty to be resolved as a condition of release
- For EMERs, the most relevant data are gathered post-release

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Model organisms may not be suitable EMER chasses

- Domesticated laboratory strain vs regulatory-exempt strains vs native microbial strains
- Model organisms and regulatory-exempt strains might not survive in relevant ecological context
- Native strains lack supporting literature for risk assessments

Challenges in implementation of meaningful data governance for EMERs

Catch-22 of data ambiguities and regulatory requirements

- Collecting and reporting of field trial data lacks consistency/ standardization
- Unclear how much data to submit and how to interpret submitted data
- Data generated from field trials is not accessible (not published, CBI, etc.)

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CBI over-designation makes the EMER regulatory record inaccessible

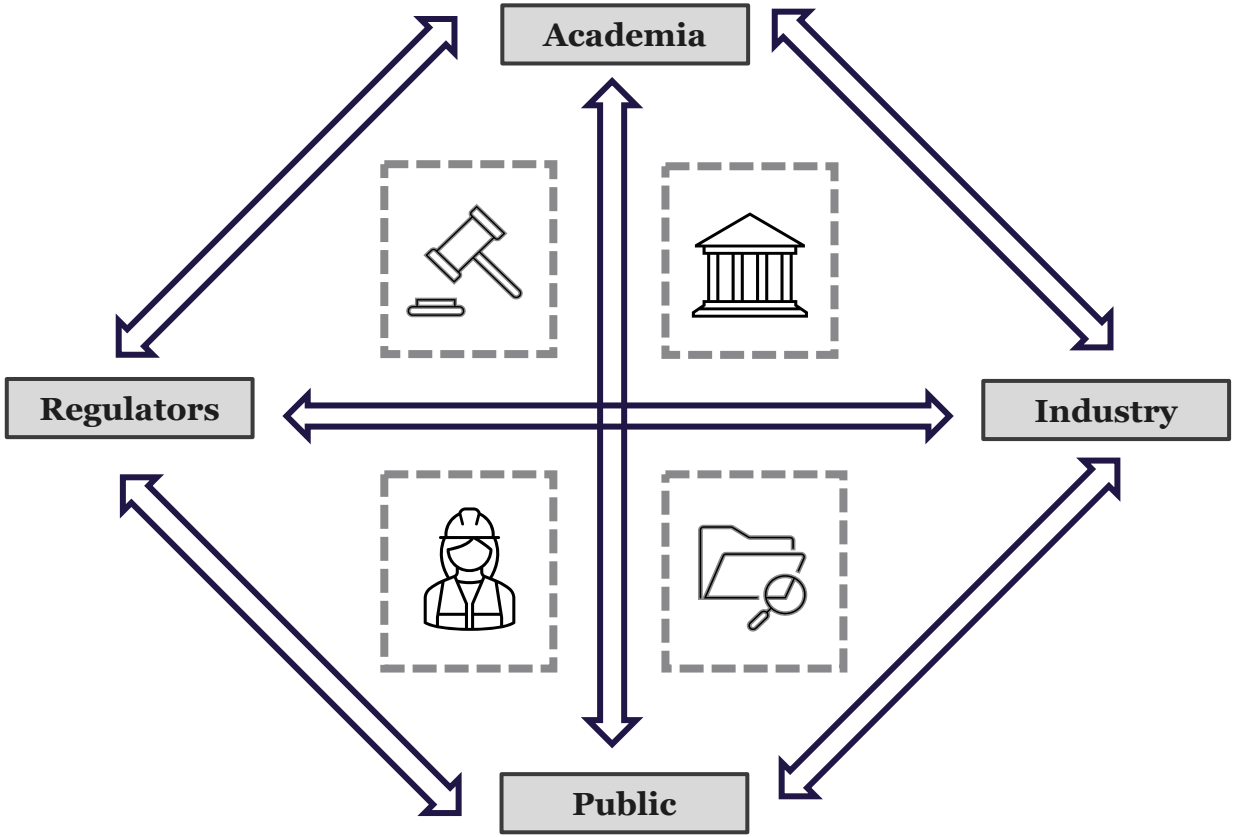
- Little incentive for developers to limit what they claim as CBI
- Health and ecological data relevant to EMER regulation is not commercially sensitive
- Barrier for interagency coordination

Challenges in implementation of meaningful data governance for EMERs

Data collection is not used for regulatory learning or risk-based design

- Sparse regulatory record prevents developers from implement risk-based design
- Elimination of EPA's Office of R&D constrains ability to generate new information
- No post-release monitoring to know whether risk assessments are well-calibrated

EMER regulation requires coordination across the stakeholder landscape



1. Reframing EMER Paradigms to Adaptive Post-Release Stewardship

1.1
EPA, USDA, NIST, OSTP to develop standardized data reporting requirements for all phases of EMER lifecycle

1.2
Establishment of publicly accessible, neutral data repository for EMER field trial and post-release monitoring data

1.3
EPA and USDA to establish formal regulatory learning mechanisms for adaptive updates in risk assessment frameworks

1. Reframing EMER Paradigms to Adaptive Post-Release Stewardship

1.4
EPA, USDA, NIST to develop mandatory post-release monitoring framework for EMERs granted field trial approval or commercial registration

1.5
Develop robust public engagement and participation programs or environmental biotechnologies and their risk assessments

2. Rebuilding Federal Capacity for EMER Oversight

2.1
Congress and the Executive Branch should restore and/or expand federal funding and staffing at EPA, USDA, and other relevant agencies for programs related to environmental biotechnology research

3. Supporting Interagency Coordination & Information Dissemination

3.1
EPA and USDA index existing guidance documents related to EMERs

3.2
EPA and USDA create interagency working group to develop an MOU for data-sharing as relevant to EMERs

3.3
EPA update 1997 guidance document on engineered microorganisms

4. Enabling Regulatory Science to Address Cross-Cutting Challenges

4.1
Congress appropriate funds to NSF, NIH, DOE, USDA-NIFA to create/restore grant programs for regulatory science for environmental biotechnologies

4.2
Agencies and national labs partner with academic institutions to established public research repository and program for regulatory science data

What could the future of EMER development look like?

Status quo (the "do nothing" approach)

- The boom-and-bust cycle of EMER interest and development will continue without new products on the market
- Advances in genetic engineering, synthetic biology, and microbial ecology will be siloed in academic laboratories, unable to resolve crises caused by climate change
- U.S. biotechnology data environment will remain fragmented→ de-prioritization of biotechnology

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Enabled by data governance for EMERs

- Data requirements can evolve and be appropriately risk-based and/or streamlined
- Iterate and calibrate risk-assessment practices
- A step towards making data-informed decisions on risk-based design (e.g. biocontainment assumptions)
- Promote transparency and build public trust

Thank you!

- National Academies of Sciences, Engineering, and Medicine
- Eric & Wendy Schmidt by Recommendation of Schmidt Sciences
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- Stephanie Batchelor
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- Stakeholder & Subject-Matter-Expert Interviewees
- 2026 Biotechnology Regulatory Fellowship Cohort