EBRC Engineering Biology Research Consortium

# Biocontainment Policy in a Robust Bioeconomy

*A Policy Paper by the Engineering Biology Research Consortium*

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The capabilities of engineering biology technologies to improve human and planetary health and well-being are expanding rapidly. Application of these technologies, such as the engineering of drought-resistant crops, bioremediation, and the control of pathogen-carrying insects could help humanity respond to climate change, clean polluted soil and water, and ensure food security.[1] However, to deliver these positive impacts, engineering biology products will need to be used beyond limited physical enclosures, necessitating appropriate biocontainment policies. While current policies are sufficient for some engineering biology products with applications outside of confined laboratory systems, other emerging technologies and applications highlighted in the EBRC Roadmap of *Engineering Biology for Climate and Sustainability* may require the clarification or further articulation of policies to be adequately reviewed by regulators. Ambiguities (both real and perceived) could discourage innovation of released engineering products, especially with early-stage developers, due to the uncertain time frame and costs required to meet regulatory requirements. Updated regulatory review should seek to identify potential unintended and damaging or dangerous outcomes so they can be assessed, contextualized, and effectively mitigated. Regulatory risk assessment should seek to optimize the benefits of engineering biology without overly restricting innovation or causing public harm. Such risk analysis should be application-dependent and may be perceived differently by the public depending on the intended use and incorporated safety precautions of new technologies. Communities that stand to benefit or bear the risks associated with the release of genetically engineered organisms should have access to ongoing discussions, technical details, and relevant risk assessments so they can participate as informed stakeholders.

Importantly, members of the research community want the products and technologies they develop to be safe and to serve a beneficial purpose. Most researchers are thus deeply invested in developing methods to embed suitable biosafety measures within engineered technologies. Such technical designs may include the confinement of products to a designated location and/or the prevention of unintentional spread of engineered genetic material, organisms, and/or systems that might persist and cause environmental harm or damage. There is a need for a strategic approach to biocontainment standards, risk assessment, and forward-thinking policy that is established jointly by regulators, researchers, and community stakeholders and that encompasses the breadth of biotechnology products and applications that should populate a safe and flourishing U.S. bioeconomy. Therefore, we recommend the following steps toward a comprehensive governance framework with sufficient biocontainment precautions that ensures safety, efficacy, equity, justice, and fairness:

[1] Engineering Biology Research Consortium (2022). *Engineering Biology for Climate & Sustainability: A Research Roadmap for a Cleaner Future.* Retrieved from https://roadmap.ebrc.org. doi:10.25498/E4SG64

## Invest in generating standards and infrastructure for appropriate biocontainment method testing and studying the potential environmental impacts of engineered technologies.

Funding agencies should continue to support scalable research on the biocontainment of engineered organisms, including quantitative methods to identify and measure potential outcomes of the escape of genetic material from engineered plants, microbes, animals, and insects. To date, few reports of escape frequencies or other relevant metrics to evaluate the usefulness and validity of biocontainment approaches have been developed and/or shared.[2] Additionally, there is a continued need to expand research for the assessment of biotechnology products in environmental contexts, in addition to building the infrastructure necessary to do so. It is important to emphasize, however, that the incomplete nature of data on the persistence and consequences of engineered organisms in all environmental contexts should not prevent the release of any engineered organisms in the environment. Rather, where we have sufficient information of environmental contexts and the properties of engineered organisms to make sufficient risk assessments now, we should do so. Many applications of engineering biology in the environment are designed to address some of our greatest environmental challenges, and failing to act when we could responsibly do so with emerging technologies is itself a significant risk.

## Create a task force to anticipate emerging technologies that may benefit from biocontainment and discuss concerns about environmentally released products.

OSTP should empanel a task force of regulators, scientific experts, and community stakeholders, including those traditionally underrepresented, to periodically consider emerging biocontainment issues, conduct horizon scanning, and outline examples of potential engineering biology-based products to help frame risk assessment parameters and approval criteria. Such horizon scanning activities could be in coordination with or incorporated into the Biosafety and Biosecurity Innovation Initiative.[3] The inclusion of each of these groups on the task force, especially representatives of the public, will ensure that diverse feedback is integrated into research and regulation and that all parties are able to voice concerns surrounding environmental and/or societal impacts of products and discuss appropriate biocontainment precautions. This task force could be informed by others, such as the World Mosquito Program, which has successfully navigated regulatory and community concerns toward improving global health and is a good example for promoting such policies and discussions. Group findings, benchmarks of risk assessment, and regulatory conclusions could contextualize engineering biology products alongside non-biotechnology comparators, similar to the European Food Safety Authority Journal.

## Conclusion

Research and development of engineered organisms or systems intended for environmental release has been ongoing for decades, yet the scale and impact of those products gained renewed prominence due to substantial progress in engineering biology. As technologies continue to advance and many focus specifically on environmental health and sustainability, the scientific community risks undermining the potential positive impact of that work by engaging too late with community stakeholders and losing public trust in technological advances and the regulatory process. Our recommendations surrounding biocontainment policy and research

[2] Perkins, D, et al. The culture of biosafety, biosecurity, and responsible conduct in the life sciences: a comprehensive literature review. *Appl. Biosaf.* 24, 34–45 (2018).

[3] See section 9 of Executive Order 14081 on Advancing Biotechnology and Biomanufacturing Innovation

serve as an added perspective when establishing a governance framework as new technologies and products emerge. Developers' and the public's confidence in a clear and thorough regulatory process are critical to accelerate innovation and expand engineering biology in the U.S. bioeconomy, creating products that are lower cost and safer than non-biological alternatives, while adhering to or exceeding the rigorous safety standards of traditional technologies and products. Building public trust goes far beyond demonstrating safety and biocontainment, but it can be aided by enabling fruitful dialogue between scientists and the public. Without action, there is a risk of restricting innovation or doing potential harm to the public and/or the environment.