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Regulatory Case-Study Analysis of Two Environmental Applications of Synthetic Biology

Emerging technologies and applications in the field of synthetic biology create unique oversight challenges for federal agencies. Many federal agencies are typically better equipped to handle reactive regulation of technologies or applications where the types of risks and benefits are known and studies have already been conducted. For synthetic biology applications, there are significant unknown elements associated with how the application will affect human health and the natural environment once released. Compounding this difficulty is the expansiveness of technologies included under the synthetic biology umbrella. In order to better inform discussions of risk governance for synthetic biology, this paper focuses on the potential regulatory options for 2 case studies of emerging, synthetic biology technologies: highly engineered microbes for biomining and for plant nitrogen fixation. By looking at these case studies, a more tangible understanding of risks, benefits and regulatory challenges that may be encountered as synthetic biology applications are deployed can be achieved. The paper uses upstream oversight assessment (UOA) for the analysis, as a subset of anticipatory governance, and focuses on the likely formal regulatory regimes and how well they are equipped to cover the potential health and environmental issues that arise from the case studies. One legal regime that will be a focus of analysis for the cases is the regulation of genetically engineered microbes by EPA under the Toxic Substances and Control Act as specified by the Coordinated Framework for the Regulation of Biotechnology. The paper will review the historical regulation of genetically engineered microbes under TSCA in order to evaluate the appropriateness of it for the two emerging synthetic biology applications.