

## **Managing the Risks of Synthetic Biology: Assessing the U.S. Regulatory System**

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### **Project Goals**

The Coordinated Framework for the Regulation of Biotechnology was established in 1986 as a “comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products.” (51 FR 23302) This framework has evolved over time (CEQ/OSTP, 2001), both as the Federal government has gained experience with biotechnology products and as the technology has advanced. However, with the advent of synthetic biology and other new technologies, new questions arise about the applicability of these rules and regulations to future biotechnology products (Rodemeyer, 2009). Synthetic biology refers to a set of techniques that together provide scientists and engineers with far greater capabilities to modify organisms than current techniques allow. The term “synthetic” comes from the relatively new ability to synthesize long pieces of DNA from chemicals, increasing both the power and precision of genetic engineering. Both the departure from older genetic engineering techniques and the broader type and scale of genetic changes may create challenges for the regulatory system.

The goal of this project is to assess how well the current Federal regulatory framework for biotechnology applies to the anticipated products of synthetic biology, and to provide options for addressing any gaps or shortcomings. This will include an analysis of the authorities that are used by regulatory agencies (primarily USDA, EPA, and FDA) as well as the risk assessment challenges that the agencies are likely to face. This is a two-year project that includes two workshops as well as multiple consultations with experts both within and outside the Federal government. The final report should be available by late 2012.

The first workshop will be held in January, 2012, and will focus on assessing the regulatory framework for likely synthetic biology products based on a case study approach. The four product case studies will be: cyanobacteria and microalgae for biofuel production; microbes for chemical production or for bioremediation; microbes for use as drugs or cosmetics; and modified plants for use as alcohol-fuel feedstock. By bringing together outside experts and Federal regulators, we hope to get a better understanding of the agencies’ regulatory authorities, their capabilities to perform risk assessments, and where any gaps in the regulatory framework may occur.

### **References**

CEQ/OSTP Assessment: Case Studies of Environmental Regulation for Biotechnology (2001). 66 FR 7905.

OSTP: Coordinated Framework for Regulation of Biotechnology (1986). 51 FR 23302.

Rodemeyer M. (2009). *New Life, Old Bottles: Regulating First-Generation Products of Synthetic Biology*. Washington, D.C.: Woodrow Wilson International Center for Scholars.

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