Synthetic Biology and the U.S. Biotechnology Regulatory System: Challenges and Options

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In recent years, a range of new genetic engineering techniques referred to as "synthetic biology" has significantly expanded the tool kit available to scientists and engineers, providing them with far greater capabilities to engineer organisms than previous techniques allowed.

In order to better understand how these products will be regulated and any challenges that may arise for the regulatory system, we undertook a study that included more than two years of research, workshops, and discussions with a wide range of experts. We explored the following questions: Will products engineered using synthetic biology techniques be regulated any differently than those engineered using older techniques? In particular, how will the regulatory agencies address the potential environmental concerns posed by the intentional environmental use of living plants, microbes, and animals engineered using synthetic biology? Are there other challenges to the regulatory system that are likely to arise from the use of synthetic biology, including likely changes in the scope, scale, or focus of the applications for these organisms? If so, what are the options that should be considered by policy makers to address those challenges?

Our research concludes that the U.S. regulatory agencies have adequate legal authority to address most, but not all, potential environmental, health and safety concerns posed by anticipated near-term microbes, plants, and animals engineered using synthetic biology. Such products are likely to represent incremental changes rather than a marked departure from previous genetically engineered organisms, and will largely be subject to the same rules and regulations that have applied to earlier generations of biotechnology. However, we did identify two key challenges posed by the introduction of these products and will present options to address each:

- Synthetic biology and other new genetic engineering techniques will likely lead to an increase in the number of genetically engineered plants that will not be subject to review by USDA, potentially resulting in the cultivation of genetically engineered plants for field trials and commercial production without prior regulatory review for possible environmental or safety concerns.

- EPA may be constrained by inadequate funding and by the authority given to it under the Toxic Substances Control Act to address the anticipated influx of genetically engineered microbes for industrial use, which could lead to regulatory delays, inadequate review and/or legal challenges.

In addition to these major challenges, we have identified three additional issues in the regulation of new microbes that should be periodically revisited as the technology advances, but, on our view, do not currently require action.

We consulted with a wide range of experts, including U.S. federal agency regulators, legal and science policy experts, representatives from the biotechnology industry, as well as a variety of non-governmental organizations to ensure a broad representation of expertise and viewpoints. This cross-section of views informed this study, but these conclusions do not represent a consensus: the findings are ours alone.