An International Look at Regulatory Oversight of Synthetic Biology: Focus on Engineered Organisms with Intended Environmental Use

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Synthetic biology is part of a new generation of biotechnology that will enable new types of products not easily achieved with today's genetic engineering. In the next 5 to 10 years, this expansion is likely to include new technologies with intended uses in the environment. Examples include organisms developed for biofuel purposes include algae that produce fuel from sunlight and plants genetically engineered for use as biofuel feedstocks. While some of these technologies are likely to be developed in the United States, product developers in other countries will employ synthetic biology and other newer generation biotechnologies as well. Moreover, product developers will be looking for production opportunities and markets for their products throughout the world. An understanding of the complex and varied regulatory oversight that currently exists for organisms engineered using synthetic biology is a necessary and vital component for understanding the societal implications of this new technology.

For example, we recently completed a report, funded by the Department of Energy and the Alfred P. Sloan Foundation, on the challenges that will arise for the U.S. biotechnology regulatory system with the increasing use of synthetic biology and other new genetic engineering techniques, with a focus on organisms with intended uses in the environment (Carter, *et al.*, 2014: http://www.jcvi.org/cms/research/projects/synthetic-biology-and-the-us-biotechnology-regulatory-system/overview/). We found that the U.S. regulatory system is well equipped to address most, but not all, health, safety, and environmental risks that these organisms are likely to pose. Our report detailed two key challenges and three additional issues that are likely to arise for the regulatory system and offered options that policy makers could consider in addressing those challenges.

The first challenge arises because synthetic biology and other new genetic engineering techniques may increase the likelihood that engineered plants will fall outside of the U.S. Department of Agriculture's (USDA's) authority to review. USDA currently regulates most genetically engineered plants because they have been transformed using a plant pest (usually *Agrobacteria*) or incorporate DNA from a plant pest. These newer techniques may no longer require plant pests for transformation.

The second challenge for the U.S. regulatory system will arise primarily for the Environmental Protection Agency (EPA), which regulates genetically engineered microbes under the Toxic Substances Control Act. As synthetic biology increases the number and the diversity of engineered microbes for commercial use, EPA's resources and expertise will become increasingly stretched. If it is not addressed, this situation could lead to delays, inadequate reviews, and potential legal challenges.

Clearly, such conclusions are specific to the United States. A comparative international analysis would help us better understand the oversight of organisms with intended environmental use are likely to face worldwide. Such organisms are subject to a wide range of risk assessment and regulatory oversight during their development and deployment that varies from country to country. However, while regulation of genetically engineered food crops has been well established in many countries, how such regulation will apply to plants engineered using newer genetic engineering techniques or for other purposes (e.g. biofuel feedstocks) is not well understood. Furthermore, while there has been some analysis of the European Union and the challenges that it faces in the regulation of newer generations of biotechnology, there has been virtually no discussion of these issues for Brazil, Argentina, and other countries that will be most likely to take advantage of the new economic opportunities that these organisms will present.

This type of analysis should focus on those countries that are most likely to embrace genetically engineered organisms with intended environmental use and/or have significant amounts of synthetic biology research underway. An initial list might include: Brazil, Argentina, UK, Germany, Spain, Israel, South Africa, Australia, and China. Some of these countries have policies and publics that are very restrictive of environmental use of genetically engineered organisms (e.g. UK, Germany), but have significant investments in synthetic biology and have also made commitments to biofuels and renewable energy. Others have less investment in synthetic biology (e.g. Argentina, South Africa), but have adopted previous generations of biotechnology for large-scale commercial production.

All of these countries and their regulatory systems exist within the complex frameworks of international treaties and agreements, import-export controls, and economic and environmental incentives. While these factors are not explicitly part of the regulatory oversight of genetically engineered organisms, they are very important in understanding the context in which these organisms will be assessed and managed. For example, how an algae-derived biofuel falls within a renewable fuel standard framework may impact its assessment in a risk-benefit analysis.

There has been limited comparative analysis of biotechnology regulatory systems (outside of the U.S. and the European Union) and virtually none in the context of newer generations of biotechnology. Such a study or studies would help to understand the regulatory pathways that these organisms are likely to face, sources of regulatory uncertainty, key economic and trade issues, and any country-specific factors that may facilitate or block development or use of these organisms as they move from the laboratory to commercial use. We hope to pursue this topic to follow up on our previous work on the U.S. regulatory system.