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Synthetic Biology Promises Risk and Reward

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In May 2010, researchers at the J. Craig Venter Institute announced the creation of the world's first synthetic organism—a bacterial host cell whose self-replicating genome was human-made. This momentous achievement raises questions regarding the potential risks and benefits of synthesizing genomes, and eventually, organisms.

According to proponents, synthetic biology offers great promise. Some scientists suggest that the emerging field could lead to advancements in individualized medicine, more efficient vaccine and drug production, new renewable energy sources, higher-yielding and more sustainable crops, and organisms that can remediate harmful chemicals in the environment. Synthetic biology is also widely acknowledged to have the potential to adversely affect human health, the environment, and national security.

The possibility for unintended environmental effects concerns Allison Snow, a professor in the Department of Evolution, Ecology, and Organismal Biology at the Ohio State University. Uncontrolled escape of synthetic organisms and the rise of new invasive species are a few of the threats, according to Snow. Given the risks, synthetic organisms will need to be thoroughly evaluated before they are moved outside contained facilities. "Ecological research takes time and funding," Snow said during a public presentation on synthetic biology in July 2010. "This is why risk assessment research shouldn't be left for the last minute. It should go in tandem as the development of these products is moving forward."

Policymakers recognize there are trade-offs between scientific advancement and societal hazard. The same day the Venter Institute's research was published, President Barack Obama directed his newly minted Presidential Commission for the Study of Bioethical Issues to provide him with a report considering the issues surrounding synthetic biology.

The president's bioethics panel released its recommendations in December 2010. The report did not call for a moratorium or additional regulations on synthetic biology research; instead, the panel called for the federal government to develop an ongoing, coordinated mechanism for the evaluation of developments, risks, and oversight in synthetic biology. According to the report, "The Commission believes that the field of synthetic biology can proceed responsibly by embracing a middle ground—an ongoing process of prudent vigilance that carefully monitors, identifies, and mitigates potential and realized harms over time." The commission recommended that this approach be led by a central body, such as the Executive Office of the President.

Currently, oversight of synthetic biology falls within existing government regulations for genetically engineered organisms and biotechnology products. Oversight and enforcement is divided among numerous federal agencies, including the Food and Drug Administration, National Institutes of Health, Department of Agriculture, Environmental Protection Agency, Federal Bureau of Investigation, Occupational Safety and Health Administration, Centers for Disease Control and Prevention, and Departments of Transportation and Commerce. Additionally, any deliberate government release of a synthetic or genetically modified organism would be subject to environmental review under the National Environmental Policy Act.

"So far, I think the current system has worked well in the US," says Snow, whose research assesses the ecological risks of transgenic crops. "GMOs [genetically modified organisms] that have been commercialized—mainly corn, soybean, cotton, and canola with just a few new traits—are widely considered to pose few new risks. With synthetic biology, which is an extension of genetic engineering, new GMOs like blue-green algae for biofuels could be more challenging to evaluate. We have less experience with these organisms and the newly invented traits they will have. It would be naïve to assume that regulations will catch every bad idea and prevent it from happening."

Experts in ethics, biosecurity, and law also see cause for concern. Some have raised doubts about society's ability to plan for low-probability, high-impact events, such as the release of a synthetic organism. Doubts linger about gaps in the current regulatory framework to oversee privately funded research, especially that of "do-it-yourselfers" who work outside of agencies, universities, and corporations.

Even if the laws were sufficient to cover synthetic biology products, the more important issue, warns Michael Rodemeyer, is "whether the agencies have the resources and tools they need to both assess the risks of this new technology and to manage the risks as well." Now at the University of Virginia, Rodemeyer was formerly assistant director for environment at the White House Office of Science and Technology Policy. "The challenge, though, particularly as the technology develops will be to develop guidelines that are sufficiently cautionary, but without imposing unnecessarily expensive and cumbersome containment requirements that might hinder research."

It remains to be seen whether or how the federal government will strike a balance between scientific discovery and risk mitigation.

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