Synthetic Biology and EHS Governance: The Coordinated Framework Case

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Liberal democracies confer to government the role of ensuring the safe introduction into society of technologies and the products of technology. In the United States, regulatory agencies that administer environmental, health, and safety (EHS) laws have been the principal actors playing this role. These agencies were set up to address 19th- and 20th-century problems, and have had notable successes in protecting people and safeguarding the natural environment. However, in the 21st century US agencies with EHS responsibilities are finding it increasingly difficult to ensure the safe and responsible introduction of new technologies into society.

The *Coordinated Framework for the Regulation of Biotechnology* exemplifies the stress that a new set of technologies, in this case biotechnology under the rubric of *synthetic biology*, has placed on EHS governance in the United States. The vulnerabilities that synthetic biology reveals in the *Coordinated Framework* also point to social science research needs around the governance of technology.

The *Coordinated Framework* was developed in 1986 as a set of policy statements organized by the White House Office of Science and Technology Policy and issued by five government units with responsibilities for biotechnology: the Food and Drug Administration, Environmental Protection Agency, Department of Agriculture, Occupational Safety and Health Administration, and National Institutes of Health. At the time, the creators of the *Coordinated Framework* believed that existing laws were sufficient to permit oversight of biotechnology. The framework therefore gave each agency with oversight responsibility wide latitude in how it implemented its regulations related to biotechnology. However, recognizing that lines of authority were not always clear, the *Coordinated Framework* established coordination among agencies with overlapping responsibilities.

The evolution of synthetic biology out of biotechnology raises concerns about the ability of agencies, within the *Coordinated Framework*, to exert effective governance over synthetic biology. For instance, under the old paradigm it was assumed that one organism would generate one product for one use, over which a single agency would have jurisdiction. Now, synthetic biology is creating conditions where a single organism may support the derivation of several products, each with multiple uses, leading to jurisdictional conflicts—or even gaps—between agencies. For example, chemical products of bacteria, yeasts or algae could have uses as food, feed, industrial chemicals, fuels, cosmetic ingredients, etc., depending on the customer and post-production processing. This is already creating problems for agencies. For instance, EPA has statutory time frames for new-substance review that could often require EPA to act well in advance of when FDA would have completed its necessary actions for a given case. This is particularly problematic because FDA nominally has the lead-agency role in many of these cases (e.g., food drug, and cosmetics cases).

Synthetic biology also raises issues related to the distinction between commercial and non-commercial research. Take the case of oversight of non-contained microorganism research that has no apparent commercial intent. Such basic research may not undergo the same type of risk-related federal review by a funding agency as would occur with a regulatory agency. Except for

compliance with National Environmental Policy Act (NEPA) requirements as exercised by the funder, generally, the focus of proposal reviews is on the likelihood of success of a given project. Funders may be reluctant to issue announcements for uncontained synthetic biology research if they believe they are responsible for risk evaluation.

The *Coordinated Framework* did not consider many issues that synthetic biology raises, such as energy policy and national security. As a consequence, agencies such as the departments of Energy and Defense, or NASA and NIST, are not part of governance under the framework.

The vulnerabilities to governance under the *Coordinated Framework* raise a number of research questions:

- Does the Coordinated Framework need to be updated to accommodate synthetic biology as a new part of biotechnology and if so, how? Would it change the overall product versus process philosophy of biotechnology governance?
- How do conflicting statutory imperatives affect implementation of the Coordinated Framework? Is the lead concept of the Coordinated Framework relevant now?
- What does "regulatory authority" over synthetic biology mean? If the United States does not have an adequate governance framework, what is in, and what is out, of agencies' regulatory jurisdictions?
- What role can nongovernmental actors play in establishing and implementing EHS governance for synthetic biology?
- What are the implications for EHS protections that could arise from decentering the *Coordinated Framework* as a primary federal governance mechanism?