Policy Innovation in Synthetic Biology Governance**

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Summary

Governance for synthetic biology (SB) is a topic of current policy discussions. This paper argues that the framing of the governance debate is overly simplistic in practice and theory, and thus governance is lagging behind technological innovation. It calls for "innovation in governance" to match technological innovation. To do so, three specific approaches are suggested. First, in the practical realm, SB has not been appropriately unpacked for meaningful conversations about governance. Disagreements in governance often arise from different conceptualizations of what SB is. In this article, the development of a typology (aka a classification system) of SB applications is suggested to move governance discussions from the very general to more nuanced, actionable items. Second, in the theoretical realm, framing SB governance as a continuum of approaches, rather than a dichotomy, is recommended to allow for stakeholders to express different values, but transcend the old, contentious, and unproductive debate over precaution versus promotion. Finally, because SB will change and develop rapidly, governance should be dynamic. Decisions about movement along the continuum should allow for more responsive governance and better opportunities for compromise among stakeholders with divergent opinions. However, these discussions should not be left only to those developing or regulating the technology, as they do not hold all the requisite expertise. A more diverse set of stakeholders and citizens with local knowledge and expertise need to be included.

Current realities

SB has made the transition from science fiction to reality. A minimal cell has been produced; undergraduate students use SB to make bacteria do novel things such as smell like bananas or take pictures; people are developing SB in their own homes; and the field is taking off in labs and markets. What remains is a sensible plan for governance. Currently in the United States, agency hands are tied by ambiguity of the SB field, politics, a lack of resources, and the fixation on decision-making based solely on the natural sciences. In addition, the science is young, especially the risk science needed for input into decisions. Moreover, current laws do not seem to be enough for safety evaluation of new and emerging products of SB, as they are already challenged by genetically engineered (GE) organisms. For example, GE insects pose an interesting case where the Food and Drug Administration (FDA) may regulate them as new animal drugs. Questions arise such as: How can a GE insect be a drug? What expertise does the FDA have in ecology and ecological risk analysis? What goes unchecked with this jurisdictional arrangement? In another example, the Environmental Protection Agency (EPA) is responsible for genetically engineered microbes (GEMs) under the U.S. Coordinated Framework for the Regulation of Biotechnology using its regulations under the Toxic Substances Control Act (TSCA). These regulations, however, do not cover "intrageneric" organisms (i.e. GEMs with engineered genes from the same genus). One could overexpress several bacterial toxins via SB in a GEM without U.S. regulation. This GEM could be deployed in the environment to perhaps remediate pollution in soils without oversight. Confidence in the U.S. regulatory system is affected by such regulatory loopholes.

Scientific opportunities and challenges

The technology has moved rapidly, but governance is lagging, especially for environmental applications like those mentioned above. While policy discussions about SB governance have increased over the past five years, the focus has largely been on biosecurity, publication standards, and DNA synthesis security standards. The publication of the H5N1 research describing how to make

a hybrid virus that moves from mammal to mammal received much public attention. Medical applications of SB have received some attention from policy scholars (e.g. bacteria engineered to fight cancer); however, agricultural and environmental applications of SB have received almost none. These applications come with very different portfolios of risk and benefit issues, ethical dilemmas, and socioeconomic impacts. The agglomeration of sectors and issues related to SB stifles progress in SB governance

Another problem stifling progress in the debate on SB governance is the precaution-promotion dichotomy. For example, precautionary thinkers (such as some ecologists, risk scientists, and consumer and environmental groups) and technology promoters (such as some bioscientists and biotechnology companies) have rigorously debated the oversight of GE organisms with little consensus built. The contested climate has sparked lawsuits by consumer organizations against companies or the U.S. Department of Agriculture (USDA) over the adequacy of environmental assessments, affected markets for products, and impacted trade.

Policy issues

- With SB products just beginning to enter markets, now is the time for anticipatory governance exercises that engage stakeholders and the public upstream of SB technological deployment. These exercises should provide a forum for diverse stakeholders to come together on neutral or balanced grounds and provide real opportunities for nuanced discussion and input into decision-making. Stakeholder and public deliberation has been demonstrated in case studies to improve the quality of decisions (NRC 1996). Engagement with real input into decisions, if done well, has been shown to increase legitimacy, bidirectional learning, and mutual respect among stakeholders. Furthermore, it is the right thing to do: in a democracy, people paying for a service have the right to be informed, be heard, and make choices about that service. Indeed, taxpayers fund the majority of SB research in academe and also pay for subsequent discoveries in industries that are based on publicly funded science and, therefore, should have input into SB governance.

- In the past, most discussions about governance of emerging technologies have been largely limited to "the science." However, by necessity, values underlie conversations about governance and it is crucial that governance discussions engage stakeholders on a broader range of ethical and societal issues.

- There is a need to unpack and to develop a typology for diverse SB applications to move governance discussions from the very general to more nuanced, actionable items. Policy debates currently fail to differentiate between specific applications of SB. However, social science research indicates that the public is unlikely to uniformly accept or reject SB and public polling indicates that the public is able to distinguish among SB applications. In our own work with nanotechnology and food applications, we found that participants in public forums care about the purpose of the technological product, the point of deployment, and the risk/benefit distribution. To facilitate meaningful discussion about SB governance options, we need more specificity. We have previously developed a typology for SB products based on sector of application (human medicine, consumer products, energy, food and agriculture, chemical production, or environmental application) and technology type (non-living biological parts, systems of non-living biological parts, highly engineered cells, highly engineered systems of living cells, artificial living cells, or systems of artificial cells) (Kuzma and Tanji 2010). Here, a third dimension is suggested: technological purpose (improve human health, improve environment, improve economic well-being, improve social well-being, national

security, enjoyment/entertainment, education, etc.). The purpose dimension might be broken down differently, dependent on the sector.

- SB governance should be framed as continuum covering preventative, precautionary, permissive, and promotional approaches. This continuum framing would allow stakeholders to transcend the old, contentious, and unproductive debate over precaution versus promotion. In prior work (Kuzma and Tanji 2010), we identified four governance policy areas (biosafety, biosecurity, ethics, and intellectual property) in which this continuum operates, with further differentiation based on the sector and type of SB technology. For example, for artificial systems of living cells released into the environment for food and agricultural applications, a preventative approach may be the first choice for biosafety reasons; whereas, for non-living biological parts used for biofuel production in the lab, a highly promotional approach may be the first choice given fewer concerns about biosafety. It is suggested here that even more nuance be added to this framework as particular SB applications are considered.

- Currently, oversight systems are almost static and, in the absence of crisis, it takes years or decades for statute or regulation development. SB requires the development of a new governance system that is dynamic and able to consider and adapt to significant new data and information as they emerge (i.e., advances in technology, biosafety, biosecurity, socioeconomic impacts, law, or ethics). While garnering the political will for such a system may take years, it will save us time and resources and promote better decisions in the long run. We suggested a similar dynamic system in the context of nanobiotechnology with principles of responsiveness, inclusion, and anticipation in previous work (Ramachandran et al. 2011). For products yet to hit the market, initial approaches to governance would be considered according to the typology and continuum analysis described above. As new information arises, a regulatory advisory group of stakeholders would convene to consider changes in governance from more to less preventative, or from mandatory to voluntary programs, or vice versa.

References

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