

Designing a “Solution-Focused” Governance Paradigm for Synthetic Biology  
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Only a few years ago, a comprehensive review of the science-policy landscape of the new products and processes of synthetic biology (SynBio) concluded that “it is very difficult to find a synthetic biology report that uses the word *risk* more than in passing, let alone directly addresses the subject at any depth” (Caruso 2008). Since then, experts in quantitative risk assessment (QRA) have begun to describe in detail the many possible adverse consequences of various SynBio products, and to estimate their probabilities and severities. The history of applying QRA techniques to emerging technologies, however, has emphasized analysis and arguably shortchanged the decision-making process that analysis seeks to fit into. In SynBio we have an opportunity to start a revolution in technology with the simultaneous transformation of governance arrangements which are fit-for-purpose—but if the assessment of risks and benefits is instead plugged into an outdated decision paradigm, we may court mistakes while missing opportunities.

In a recent National Academy of Sciences report (NAS 2009) and a subsequent article (Finkel 2011), I have advocated for turning the 1983 “Red Book” risk management paradigm on its head: instead of assessing risks until exhaustion and then beginning to map the insights from assessment onto decision-making, I argue we should *first* consider the spectrum of plausible solutions to environmental, health, or safety problems and then direct scientists and economists to analyze the benefits and costs of each possible decision. This approach makes risk assessment (and economic analysis) more useful, but it also allows us to contemplate ambitious solutions that can reduce multiple risks in concert, rather than defining each problem as merely the nuisance of one particular substance in one environmental medium. For example, applied to the problem of bisphenol A in water bottles, the “Red Book” approach could result in an exposure limit; a more expansive life-cycle approach could involve a discussion of the comparative risks of different plasticizers, or perhaps expanding the list to include aluminum bottles, whereas the solution-focused approach could start with looking for better ways to provide consumers with ready access to cold drinking water, perhaps without the need for so many disposable bottles.

Applied to SynBio, “solution-focused risk assessment” is a way to jump-start a broad and evidence-based management of emerging applications in order to maximize net benefit and promote distributional equity. In this framework, society could look first to each human need that SynBio promises to fulfill, and consider that we could tolerate risk in proportion to the *unique* benefit that the SynBio product/process offers.

This presentation will introduce five case studies of a solution-focused approach to specific SynBio applications that the author and colleagues at the University of Michigan hope to undertake over the next 15 months under a proposed foundation grant.

Caruso, Denise (2008). [\*Synthetic Biology: An Overview and Recommendations for Anticipating and Addressing Emerging Risks\*](#) (Washington, DC, Center for American Progress, 2008).

Finkel, Adam M. (2011). “Solution-Focused Risk Assessment: A Proposal for the Fusion of Environmental Analysis and Action.” *Human and Ecological Risk Assessment*, **17(4)**:754-787 (and 5 invited responses/commentaries, pp. 788-812).

National Academy of Sciences (2009). **Science and Decisions: Advancing Risk Assessment**. Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, National Academy Press, Washington DC, 403 pp.