## Case Studies Applying the "Solution-Focused Risk Assessment" Paradigm to 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 have made some progress describing the many possible adverse consequences of various SynBio applications, although few analyses have attempted to estimate the probabilities or severities of these potential harms. As this work progresses, however, it will be crucially important not to fixate on the potential harms in isolation, but rather to ground them in a sensible weighing of risks, benefits, and alternatives.

The history of applying risk assessment techniques to emerging technologies has arguably shortchanged the decision-making process that analysis seeks to fit into. In SynBio we have an opportunity to begin a revolution in technology with the simultaneous transformation of governance arrangements to ones that are fit-for-purpose—but if the assessments of risks and benefits are instead plugged into an outdated decision paradigm, we may court mistakes while missing opportunities.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 proposed turning the 1983 NAS "Red Book" risk management paradigm on its head. For example, applied to the problem of bisphenol A (BPA) in water bottles, the "Red Book" approach could result in an exposure limit for BPA, while 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. But a solution-focused approach would start by reminding us what we are trying to do in the first place—here, seeking to give consumers ready access to cold drinking water—and this might prompt discussion about how we might help return the market to the day when Americans *weren't* trucking 9 billion bottles of water (it falls from the sky, apparently) to and fro every year, and throwing most of them into the ground soon after using them.

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 a SynBio application promises to fulfill, and consider that we might tolerate novel risk in proportion to the *unique* benefit that the SynBio product/process offers.

This presentation will introduce six case studies of a solution-focused approach to specific SynBio applications that the author and colleagues at the University of Michigan are currently examining. Cases include ethanol production using algae, modified intestinal flora to reduce the infectivity of chlolera, engineered mosquitoes to prevent dengue fever, and bio-isoprene synthesis.

## References

Caruso, Denise (2008). <u>Synthetic Biology: An Overview and Recommendations for</u> <u>Anticipating and Addressing Emerging Risks</u> (Washington, DC, Center for American Progress, 2008).

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