182. Risk and Escape Policies, Perspectives, and Practices: Issues and Implications for Biosystems Design R&D on Microbes, Algae, and Plants

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Project Goals. This project aims to identify circumstances that influence the human health and environmental risks associated with biosystems design research and development (R&D). Inquiries focus on research practices that help assure that new biological entities are safe to humans and the environment. We investigate the array of known and potentially unknown risks, and the potential for unintended adverse consequences, from two main categories of perspectives. One category is the set of perspectives of key players in biosystems design R&D, particularly scientists engaged in that R&D and biosafety professionals. The other category is the varied physical and institutional contexts in which biosystems design R&D takes place. Through analyses of research practices associated with both the "doing" of R&D as well as the development of safe biological organisms and systems, we seek to identify opportunities for avoiding or managing health and environmental risks.

The DOE Office of Science rationale for its investment in biosystems design (synthetic biology) R&D includes the following statement. "The merging of biology, chemistry, physics, and engineering has the potential to transform fundamental and applied science by shedding light on the basic principles of biological system organization and evolution…." (http://genomicscience.energy.gov/biosystemsdesign/). However, "the potential to transform" also carries the potential to create human health and environmental risks. The manifestations of such risks, of course, are conditioned by circumstances that affect their extent and impact—circumstances like those embedded in varying R&D contexts. Our research looks at linkages between R&D contexts and risks from a social and institutional perspective. That is, we investigate how components of R&D context (research setting, research approach, and organism studied, etc.) shape real- world research practices in ways that may contribute to or reduce the environmental and health risks associated with biosystems design R&D. We place particular emphasis on circumstances that inadvertently amplify or create risks during the course of R&D and with regard to the development of new biological organisms or systems.

To achieve our goals, it is essential to understand concepts of "risk," "containment," and "escape." There are ambiguities and differences associated with each of these terms when they are applied to biosystems design R&D. This kind of analysis helps to illuminate and understand connections between research practices and risks—whether during the conduct of R&D or with regard to the biological entity being designed. For example, we sort our information by the three broad categories of organisms that are the subject of DOE-funded research: microbes, plants, and algae. It may seem obvious that both human health and environmental risks associated with biosystems design R&D vary according to the type of organism at issue. However, a surprisingly large subset of the risk-related literature either fails to distinguish among organisms or implicitly seems to refer only to one category of organism (e.g., microbe). "Containment" translates into divergent terms when thinking about microbes versus plants versus algae; open- versus enclosed research settings; and a tool of research (e.g., bioreactor) versus a strategy for risk management. "Escape" becomes a muddied topic when comparing different circumstances. Take, for example, horizontal gene transfer (HGT), which sometimes is undesirable form of escape but sometimes is a desired research outcome.

We have begun to "unpack" these terms by analyzing them from multiple standpoints. Our data sources are published scientific literature, regulatory and biosafety guidelines, and interviews we conduct. This

information guides our inquiries about research practices and helps us analyze where gaps may exist.

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