

Table 1. Summary of five main research categories for environmental risk assessments of synthetic biology applications. Generated by participants at the Comprehensive Environmental Assessment and Synthetic Biology Applications Workshop, Woodrow Wilson International Center for Scholars. July 28, 2011

<b>Research category</b>	<b>Specific questions</b>	<b>Vote tally</b>	<b>Reasons given by participants</b>
Rates of evolution and changes in functionality	<ul style="list-style-type: none"> <li>Investigate the rate of evolution for changes in functionality.</li> </ul>	0	NA (no votes)
Survival and persistence of the organism	<ul style="list-style-type: none"> <li>Is the organism compatible with the environment and other populations?</li> <li>Can the organism survive in a dormant or resting state?</li> <li>What is the “fitness cost” of the engineered gene and how much of a fitness cost would encourage rapid fall off or “extinction” of the organism in the wild?</li> <li>How many survival competition tests do we need? Studies should include a whole community analysis, under a variety of env conditions. Consider everyone (the grazers), not just the competitors.</li> </ul>	5	<ul style="list-style-type: none"> <li>Encapsulates the genetic history of organism and be useful in understanding its evolution.</li> <li>Companies are not expected to do a lot of work in this area; this information is difficult to come by, but important.</li> </ul>
Fate and transport of functional genetic material	<ul style="list-style-type: none"> <li>Ability of DNA to persist after death?</li> <li>What may acquire the gene?</li> <li>Does the target gene remain functional in other hosts?</li> <li>In what ways can the target gene alter existing genomes?</li> </ul>	11*	<ul style="list-style-type: none"> <li>A non-scientist would be very interested in this. A risk assessment would certainly need to cover this to satisfy the public.</li> <li>Fills in gaps, leads to useful information for both regulation and development of organisms.</li> <li>Least understood of what we talked about today and therefore most interesting.</li> </ul>

	<ul style="list-style-type: none"> <li>• Introduce fragments of the introduced cassette and measure what is picked up by other microorganisms.</li> </ul>		<ul style="list-style-type: none"> <li>• Most relevant from the policy perspective.</li> <li>• A risk we don't understand</li> <li>• * limiting fate of genetic material</li> </ul>
Physiological differences and functionality between the wild and novel organism	<ul style="list-style-type: none"> <li>• What is the natural risk of these wild organisms?</li> <li>• How do we compare the additional risk due to novel genes?</li> <li>• Investigate secondary metabolites. How many should we look at and at what concentrations?</li> <li>• What are cells doing on a daily basis? Have they changed? Are they the same cells you started with? Are they behaving as desired?</li> <li>• Generate a profile of how the genome and the products of the cell are changed by the addition of engineered genes.</li> </ul>	9	<ul style="list-style-type: none"> <li>• Captures a broad understanding of the organism before it is modified and allows you to compare your modified organism to something.</li> <li>• By focusing on this category, we would be addressing issues contained in research categories 1 and 2</li> <li>• Need to know before we can say if the new organism will change ecosystems</li> <li>• This category has the least amount of available data</li> <li>• This represents the hazard part of the risk assessment which is important</li> <li>• This will be the trigger of regulation</li> <li>• This information is important for the 1st step for the risk assessment and will temper what questions you ask in other areas</li> </ul>
Probabilistic modeling of gene transfer	<ul style="list-style-type: none"> <li>▪ Can modelers guide the parameters and data needed to predict gene uptake?</li> <li>▪ Would a model separating naturally occurring genes prevalent enough to assume that they have been thoroughly sampled throughout evolution from ones that are rare be useful? Can we create a threshold of exoticism for genes to guide us?</li> </ul>	0	NA (no votes)