GES Center Report #2015.2

NC STATE GES

Synthetic Biology Governance: Delphi Study Workshop Report

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Hosted by the Genetic Engineering and Society Center, North Carolina State University, with funding from the Alfred P. Sloan Foundation program on Synthetic Biology

Alfred P. Sloan FOUNDATION

1. Introduction

Synthetic Biology (SynBio) involves applying engineering principles to the fundamental components of biology in order to construct novel or modified biological systems for beneficial purposes. As a scientific discipline, SynBio has an opportunity to benefit society in areas such as agriculture, medicine and environmental protection and remediation. However, it is expected to be controversial for several reasons, including value-based objections and potential health, environmental, and socioeconomic risks. Appropriate governance mechanisms have the potential to minimize harm and improve the chances for broad public benefits from SynBio, while respecting a range of societal values.

In order to explore risk governance data needs, opportunities, and challenges for SynBio, we initiated a research project funded by the Alfred P. Sloan Foundation in 2013. This project had the overarching goals to "unpack" the broad field of SynBio for more nuanced and productive policy discussions and help set priorities for risk-relevant data collection, organizational and/or legislative readiness for oversight, and public and stakeholder engagement. In doing so, the project chose four case studies of potential applications of SynBio that are not yet in final stages of research and development. We employed a four-round policy Delphi study to anticipate governance needs upstream of technology development and consumer use. A policy Delphi does not require participants to come to agreement on the issues necessarily, but rather strives to identify and explore options or alternatives for addressing the issues (Turoff 1973), in this case SynBio risk governance. Delphi methods are particularly suited to envisioning futures in the face of high degrees of uncertainty and draw upon subject matter experts as a data source in these areas.

The Delphi study group involved 48 participants from diverse disciplines and organizations with backgrounds in technical, policy or societal dimensions of genetically engineered organisms and/or SynBio. The Delphi took place in four rounds: interviews, survey #1, workshop, and survey #2. The workshop included small and large group dialogues and mapping exercises to evaluate data needs for risk governance for each of the cases, to examine appropriate and ideal governance systems for each of the cases, and to identify opportunities and barriers for risk governance of SynBio. The conversations and ideas from the workshop phase are reported here.

The Delphi study furthers the goal of Sloan's Synthetic Biology initiative designed "to identify the risks associated with research in and applications of synthetic biology and to assess the ethical, regulatory and public policy implications of these risks"[i]. A primary objective of the study was to identify associated uncertainties and assess their possible implications on oversight as well as to determine how to sufficiently utilize risk analysis methods and oversee products of SynBio in the face of such uncertainties. The policy Delphi process was used to explore attitudes towards the futures of the SynBio applications and to identify and evaluate options for risk analysis and governance. The project team is in the process of publishing several journal articles based on outcomes from the interview and survey phases of the Delphi. This report serves to capture the main ideas and concept maps from the workshop.

2. Workshop Description

The workshop portion of the study was held on June 3-4, 2014 at North Carolina State University's (NCSU) James B. Hunt Library on Centennial Campus. Of the 48 participating experts in the study, 29 were able to attend the day and a half long workshop along with 11 NCSU faculty, staff, and graduate students from the Genetic Engineering and Society Center, for a total of 40 participants. Participants were affiliated with a range of sectors including university, industry, non-profit, and government. Each participant provided insights from their specific areas of expertise including public policy, molecular biology and genetic engineering, law, sociology, ethics, religious studies, science and technology studies, toxicology, human health, ecology and environmental science. Workshop activities included small and large group discussions, along with concept and mind mapping exercises, with the goal of discovering data and research needs as well as ideal governance options for four case studies of SynBio: Biomining, Cyberplasm, Deextinction, and Nitrogen Fixation, and two broader categories of SynBio applications: General Agricultural, and General Environmental Applications. When creating the small groups for dialogue at the workshop, participants were arranged so that each group was comprised of representatives from several areas of expertise and organizational affiliations.

2.1 Purposes and Premise

The purpose of the workshop was to provide open face-to-face dialogue between the multidisciplinary panel of experts about the governance of SynBio as a complement to individual responses (surveys and interviews) from the Delphi study. In fostering a collaborative and respectful environment, ideas emerged about data and information needs, as well as variables to consider, policies, and processes for governing the next generation of SynBio applications.

The workshop agenda included the following activities:

1. Review preliminary results from the first rounds of Delphi study (interviews and survey #1)
2. Engage in mapping exercises to conceptualize relationships between governance issues and decision making needs,
3. Envision ideal governance systems for SynBio applications, and
4. Identify barriers and opportunities for implementing governance systems.

2.2 Conduct

The workshop was conducted under Chatham House rules in that comments, quotes, and contributions were not attributed to individual participants outside of the workshop. Visual maps and models were also not attributed to individuals and were used for research results and reporting only. The workshop participants were assured anonymity in their comments according to the IRB protocol for the Delphi study. Participants were given the option to list their participation in this report, and those in the appendix volunteered to do so.

2.3 Outcomes

The intended outcomes of the workshop were the identification of research, data, and information needs for SynBio cases; governance needs; and barriers to and opportunities for achieving responsible governance. Collaborative systems mapping (Cockerill et al. 2009) was used as a dialogue tool for sparking ideas and ways of looking at the connectivity of the issues surrounding SynBio governance.

3. What data and information is needed for governance?

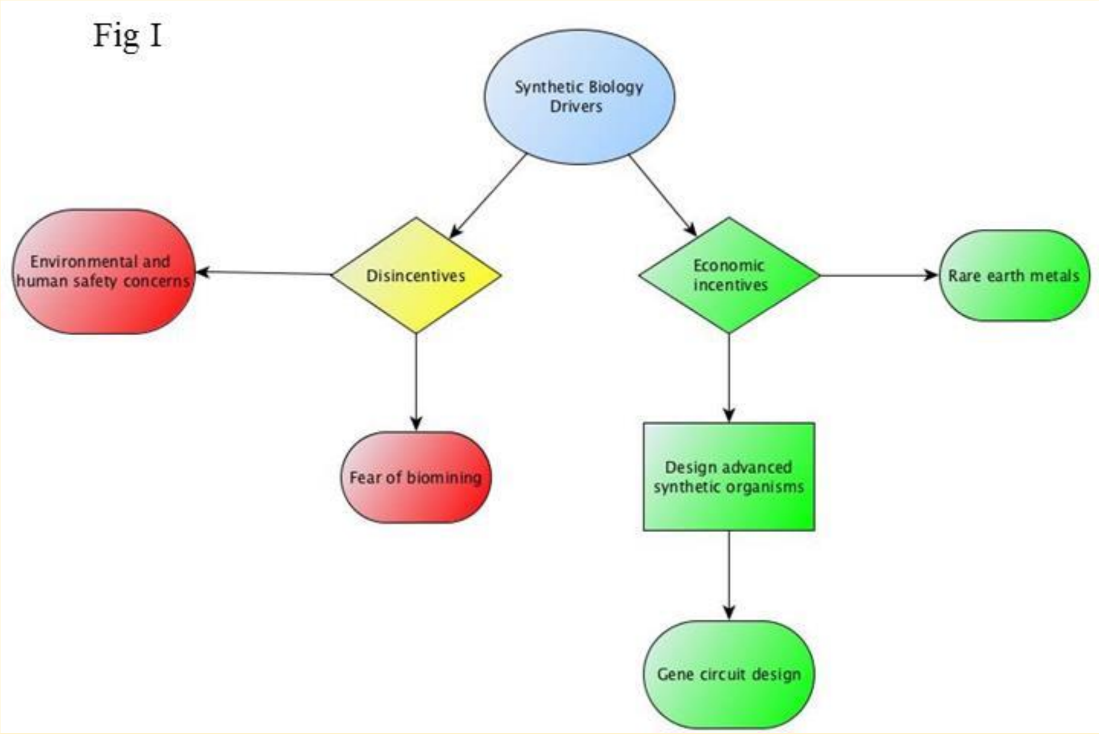
Four specific cases were used to anchor the discussions; they are detailed below. This approach was inspired by previous experiences and literature on the difficulties of discussing issues surrounding SynBio governance when the technologies and all their applications are considered as a whole (Kuzma & Tanji 2010). These cases were also used in the full Delphi study at each stage. At the workshop, two more general situations were added: the use of SynBio for general agricultural applications as well as for general environmental applications. Below is a description of the 4 cases, the two general cases, and the results from the first question of the workshop: what data and information are needed for governance (for this case)? We instructed the participants not to limit themselves to the discussion of direct human health and environmental risk or benefit data, but also to consider socioeconomic, cultural, and ethical information needs, as well as indirect harms and benefits.

A. Biomining

Biomining involves the use of microorganisms to extract rare and base metals from minerals and ore. For example, *Acidithiobacillus ferrooxidans* and relatives are able to assist with biooxidation and bioleaching of many types of minerals for mining. Genetic engineering is now being applied to enhance these processes, and research has been conducted to engineer microbes for increased redox potential and leaching rates (Brune & Bayer 2012). Researchers and companies, such as Universal Biomining, are working on SynBio techniques to create microorganisms better designed for metal extraction (Universal Biomining 2013). Genetically engineered microbes could be used *in situ* in the mining environment or as part of processing in a plant. Participants were asked to consider the *in situ* environmental release and use of highly engineered microbes for biomining in this case study. Figure I depicts a systems map generated by the workshop participants to consider the research, data, and information needs.

During group discussions a major theme that emerged was whether or not the microorganisms can move outside of the targeted release area, and if so how long are they able to live? Much of the discussion focused on issues related to bio-persistence and organism stability in the environment. The majority of participants agreed that data are currently unclear regarding how to design organisms that only survive a short time but whose genetic material may persist in the environment.

One of the major questions that arose from the workshop discussions was: ***How long does the organism last in the target environment?***



Participants noted several risk management issues regarding bio-persistence, asking ***"is it possible to produce economically viable 'suicide' gene traits/organisms which can be easily signaled outside of the target environment?"*** Another theme discussed concerned the capturing of toxic build up from the organism- "can the organisms used in biomining leach through to the water table?" Needs were identified for biological processes to minimize waste and/or leaching and to maximize the extraction of the product from mining wastes. Participants also discussed the role of predictability as it pertains to biomining. Some questioned the definition of "predictability" itself, and another further noted that predictability, and specifically the inefficient means for accurate predictions, applies not just for natural world phenomena, but also to regulation systems and risk management mechanisms.

Broader discussion included issues of "rare earth metals" and industrial globalization. Participants raised questions about the diminished US production of rare earth metals when compared to other powerful countries, and how issues of national security may become more imminent in the future should mining of rare earth metals continue to be dominated by other countries. Participants noted that biomining might swiftly become a means to improve US initiatives to access rare earth metals.

Regulatory questions focused on which US government agencies would be primarily responsible for overseeing this technology. The US Department of Interior's (DOI) Bureau of Land Management (BLM), the Environmental Protection Agency (EPA), and the importance of both state and federal oversight were raised. EPA has authority for genetically engineered microbes under the Coordinated Framework for the Regulation of Biotechnology through the Toxic Substances and Control Act (TSCA), and microbes engineered from newer SynBio methods would likely encounter the same regulations (Carter et al 2014). DOI-BLM has a long history of mining oversight and there are numerous regulations and several other federal and state agencies that would be involved. Thus, the legal authority for biomining was not fully settled by the workshop participants. A broader concern voiced by some participants was ***whether oversight would continue to be housed by institutionalized regulatory silos or if the process would be more collaborative and dynamic.***

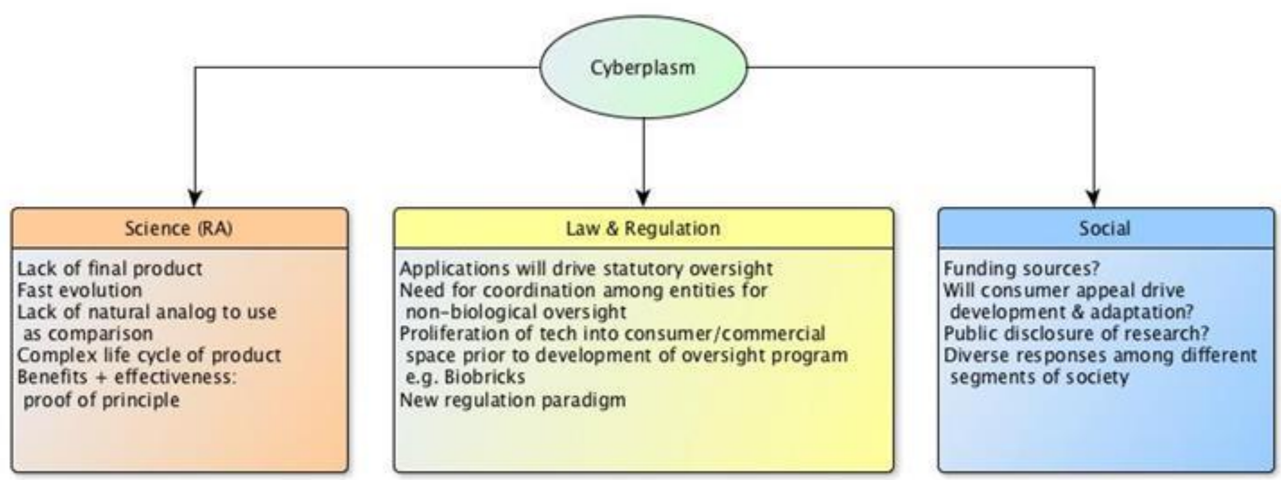
Participants also discussed the biochemical and genetic make-up of the organisms that would be used for biomining. Some were concerned that the organism and the processes used in biomining may pose new issues concerning worker safety, while others noted that the entire process of biomining would likely diminish many of the risks of mining itself and lower human death tolls due to reduced chemical usage and likelihood for traditional mining accidents. A ***full risk-benefit, cost-benefit, or risk-risk analysis would be needed for specific cases of biomining to determine the health impacts and tradeoffs compared to conventional mining***.

B. Cyberplasm

Defined loosely as an engineered (micro)-organism that could detect its environment, Cyberplasm integrates engineered bacteria, yeast, and mammalian cells and cell parts to undertake device-like functions capable of sensing and treating pathogens or chemicals within plants and animals, or for other functions involving environmental sensing and remediation (e.g. Ayers et al. 2010). Cell parts for detection, signaling, motion, and delivery would be integrated into a biogel matrix to mimic the movement of the sea lamprey. The project originated from a "sandbox" designed by the National Science Foundation (NSF) and Engineering and Physical Sciences Research Council (EPRSC) in the UK to produce transformative ideas with a low probability of succeeding. The Cyberplasm project was chosen as one of the 5 funded and is an example of a conceptual and complicated interdisciplinary SynBio project. Work is now being conducted on the parts of the artificial organism. Researchers have speculated, that in the long-term, Cyberplasm could eventually impact the healthcare industry by improving the biosensors and drug delivery systems through cellular machines (NSF grant #0943343). However, they also note that the main aim of the project is to provide heuristic value to "impact the imagination of the general public, the private sector, and education in general" (NSF grant #0943343).

During the workshop, participants noted that basic risk analysis methods exist for micro-organisms in the environment and food, but there is high uncertainty here due to lack of the final product composition and purpose, the lack of a "natural" analog to use as comparator, and historical precedent of a non-replicating machine made of biological parts. Some participants were concerned that the potential benefits of Cyberplasm development were mainly for scientific advancement and proof of concept rather than applications that are more directly targeted for pernicious contemporary health and environmental issues. Many participants questioned the tradeoffs made in supporting work on Cyberplasm and questioned, "***What important technological applications are not being developed as a consequence of Cyberplasm funding?"*** In the systems mapping exercise, the Cyberplasm group participants identified broader scientific, regulatory and societal questions for gathering research and information (Fig. II).

Fig II



There was disagreement on the feasibility of a medical (diagnostic or treatment) application of Cyberplasm, and many participants noted that it might be more readily deployed for environmental applications. Therefore, for the purpose of furthering discussion, agreement was reached that this technology might be used for the purpose of environmental remediation and sensing. Several participants stressed that data concerning the application itself are sorely lacking, and therefore it is difficult to assess health or environmental risk data needs. Some questions that arose during other phases of the workshop and study included the ability of the cellular components of Cyberplasm to survive in the environment even though the device itself is non-replicating, the allergenicity and toxicity of the components that may travel through environmental systems (e.g. in wastewater, or runoff), and human health effects of ingesting Cyberplasm if it is intended for medical use. ***Life-cycle analysis was thought to be important for this case study such as the exposure, toxicity or allergenicity of breakdown products through the product's use, possible component replication, and degradation in the environment.***

Given the early stage of development of Cyberplasm, the participants focused more on the degree of regulatory attention that should be given to technologies that are years or decades away from open use and dissemination. Others questioned the applicability of current regulatory structures to oversee technologies being developed that do not yet have a definitive use. ***There is an important dilemma presented by this case: wanting to be prepared for governance of future technological advancements while facing the difficulties of identifying risk analysis and regulatory needs without a specific product in hand.***

It was agreed that the application domain (health care vs. environmental) will drive statutory oversight, but that there also will be a need for coordination between agencies. Some participants noted that ***laws and governance concerning Cyberplasm will need to be based on specific applications of the technology and that this may require new regulatory mechanisms and structures concerning the hybridity of the application***. Finally, the group noted that public opinion will be important for this technology, and public reaction may be evoked by its robotic and "artificial life" features. Proper engagement with public audiences to improve discourse and communication between stakeholders was suggested. Participants also noted, however, that commercial appeal will likely drive development.

C. Deextinction

Deextinction is the process of inserting recovered, edited, or synthetic DNA of extinct organisms into a host egg in order to recreate the extinct species. This process requires well preserved DNA either for sequencing, editing, or use for engineering embryos. With data on the sequence of the whole genome of an extinct animal, DNA sequences of that animal could potentially be synthesized, or new genetic engineering techniques, under the rubric of "gene editing" could be used, to alter genes from existing and related species. One idea is to start with the genome of a closely related organism that is still living and use gene editing to turn it into something closer to the genome of the extinct animal. Then that genome would be transformed into a de-nucleated and fertilized egg of the living relative to bear the offspring of the extinct animal. Some scientists and conservationists are taking deextinction projects more seriously than in the past, because of the new potential of quick DNA synthesis and editing. Together they have created guidelines for choosing and developing deextinction projects, and proposed species include the passenger pigeon and woolly mammoth (Seddon et al. 2014).

Out of all the case studies, the participants voiced the need to discuss the ethical and broader societal issues associated with evaluating this technology prior to development. Key issues included the rights of humans to recreate extinct ecosystems***, the opportunity costs of investing in deextinction above conservation, and low fitness of fetuses during the cloning process used for deextinction. Additionally, discussion ensued regarding how genetic variation will prevent the recreation of organisms identical to the extinct organism, dual use and security issues with recreating harmful species for nefarious purposes, and unanticipated impacts of revived organisms as potentially invasive species in existing ecosystems.***

Public reaction to the "science fiction" nature of the project was also a predominant issue. Some participants believed that public perception might be heavily influenced by popular culture references to movies like *Jurassic Park* (or *Jurassic World*), where things invariably go wrong with species recreation. Participants in this group also questioned who is doing deextinction research and exactly what their motivations are for such work. They noted that clear ethical and moral evaluations should occur, and that especially for this case study, public and stakeholder engagement should be a pre-requisite for any deextinction project.

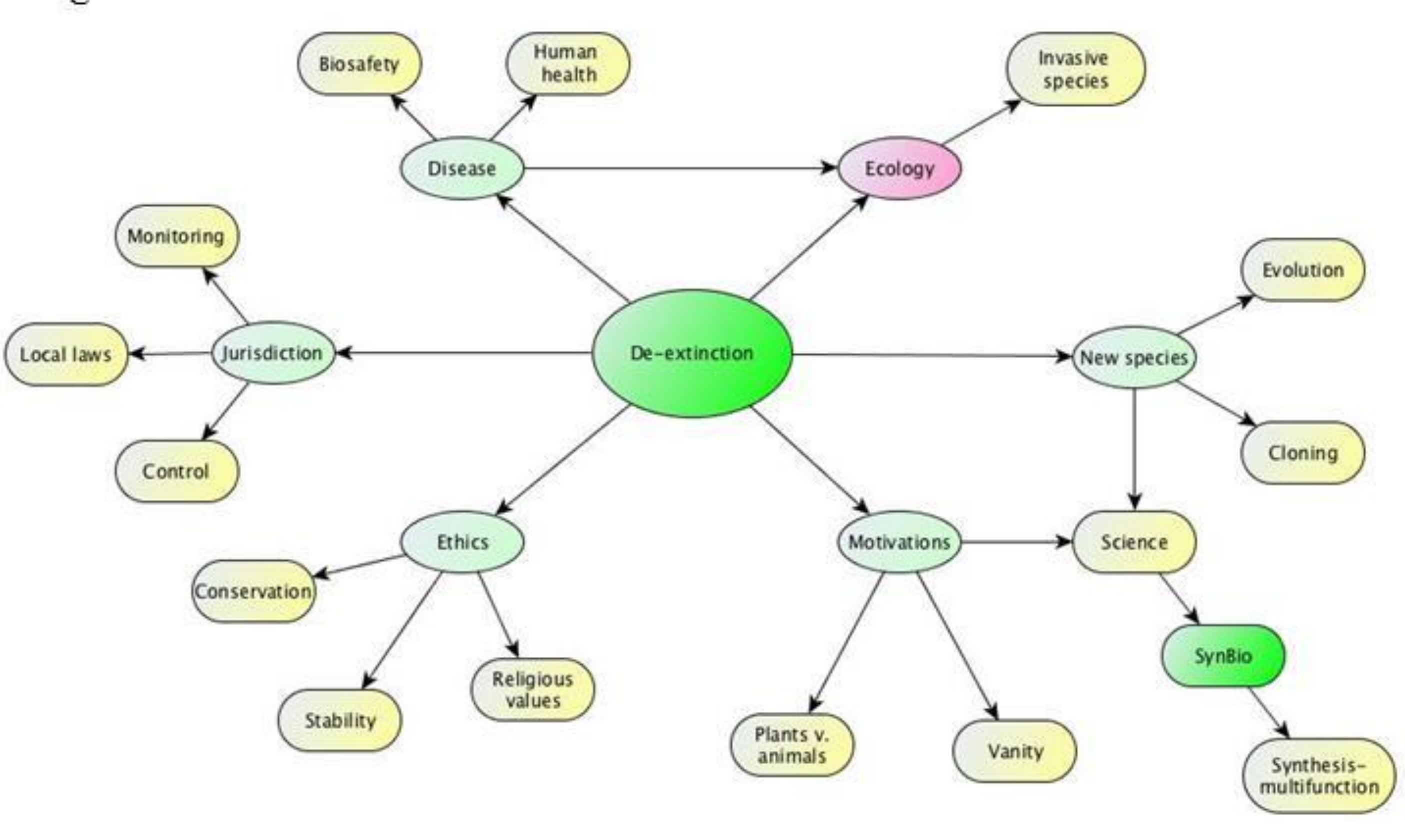
Ecosystem risk issues were also identified. Questions were raised, including: What happens when a once-extinct organism is introduced into a new environment? ***Are modeled systems viable for assessing risks? What jurisdiction issues will likely arise given organism migration across state***

and international borders? Above all, the participant group noted that there are many layers of complexity given this case that need further investigation prior to open release (Fig. III). Other questions posed by this group included:

- How are distinctions made regarding which species should be recreated?
- Is it up to us to undo harm that has been done?
- Risk/benefits- who does risk fall upon?
- Complexity- should there be a distinction between dual use and legitimate public projects in assessing risk?

The systems map for the issues associated with this case was more complex than the others, lending to the deep integration of the moral, ethical, and natural-science based risk questions.

Fig III



D. Nitrogen Fixation

Increasing world populations are leading to a greater need for new and improved food crops. The challenge is how to meet these needs in an environmentally sustainable way. Some scientists and technologists are turning to microorganisms as a possible avenue for improving large-scale agriculture. A wide diversity of microorganisms colonize plants. These microorganisms can have a profound effect on food crops as microbe interactions can either benefit or harm plants depending on the encounter. For instance, densely colonized soil contains beneficial fungi and rhizobia bacteria which symbiotically associate with roots and provide plants with mineral nutrients and fixed nitrogen, respectively, in exchange for carbon. Some scientists and technologists propose to employ techniques from the field of SynBio to catalogue and engineer microorganisms with desired characteristics for crop production and nitrogen fixation. Engineered microorganisms are being designed to manifest a variety of outcomes in food production including improved plant growth, yield, and efficacy, and protection from a variety of plant pathogens and environmental conditions.

One example the group at the workshop considered for this case study was to improve or extend upon the symbiotic relationship between crops such as legumes and nitrogen-fixing bacteria. Multiple genetic manipulations could make possible new symbiotic relationships wherein microbes that already have the ability to fix nitrogen can interact with a plant that does not already possess the ability to host the microbe, or plants themselves could be engineered to associate with nitrogen-fixing bacteria. Benefits of this technology include decreasing global nitrogenous fertilizer demands and increasing crop yields. Together these benefits could potentially offset the environmental degradation caused by fertilizer application. In one such example, the bacterium *Mesorhizobium loti* is being engineered to improve nodulation on rice crops, thus allowing the two to enter into a symbiotic relationship where the *M. loti* colonize the newly formed nodules of the rice crop and provide a readily usable form of nitrogen. The case study used in the workshop, genetically modified bacteria for nitrogen (N) fixation in non-legumes, is an ongoing research effort in SynBio (Oldroyd & Dixon 2014).

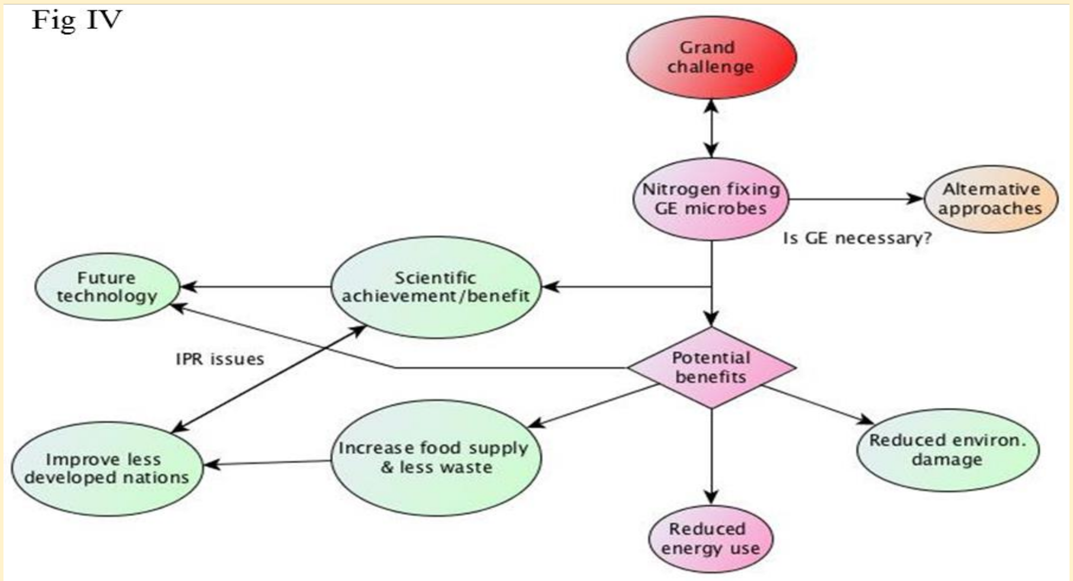
Discussion among participants in this group was wide ranging, beginning with the overall question of whether SynBio technology is needed to improve N-fixation instead of using other biological systems, such as mixed plantings of legumes and non-legumes. The group noted a pressing need for additional information on risk and benefits of SynBio approaches compared to the ecological impacts of fertilizer applications. One question addressed the evolutionary process of plants asking, why nature did not already improve N-fixation. In other words, should we be introducing this technology widely when it makes an evolutionary leap forward***? Can alternatives without SynBio be introduced more effectively***?

Nitrogen fixation and nodulation pathways are biochemically and genetically complex. This subgroup discussed the increasing complexity of genetic engineering and the resulting products through synthetic biology approaches and what affect complexity has on the risk assessment process. There would need to be data and information related to whether the complexity is controlled. The use of natural homologs to SynBio bacteria for assessment, considerations of whether traits are pulled from "natural systems", and evaluation of the genomic, ecological, and metachemical consequences of complex engineered pathways were raised as key points. The group raised the question of ***what the consequences are of gene flow or bacterial dispersal in the environment. In other words, assuming that it happens, does it matter?***

This group noted many potential benefits of the technology. ***Some argued that SynBio "fertilizer" could be considered more natural for environmental systems than chemical fertilizer alternatives***. The group also noted ***that nitrogen pollution prevention could be a potential benefit to this technology***. Additionally, the group thought that the technology could be feasible in less developed countries where the benefits would be more widespread. Finally, participants noted that emerging economic drives are likely to follow the widespread use of this technology and that it may open new markets not currently available for traditional agriculture industries.

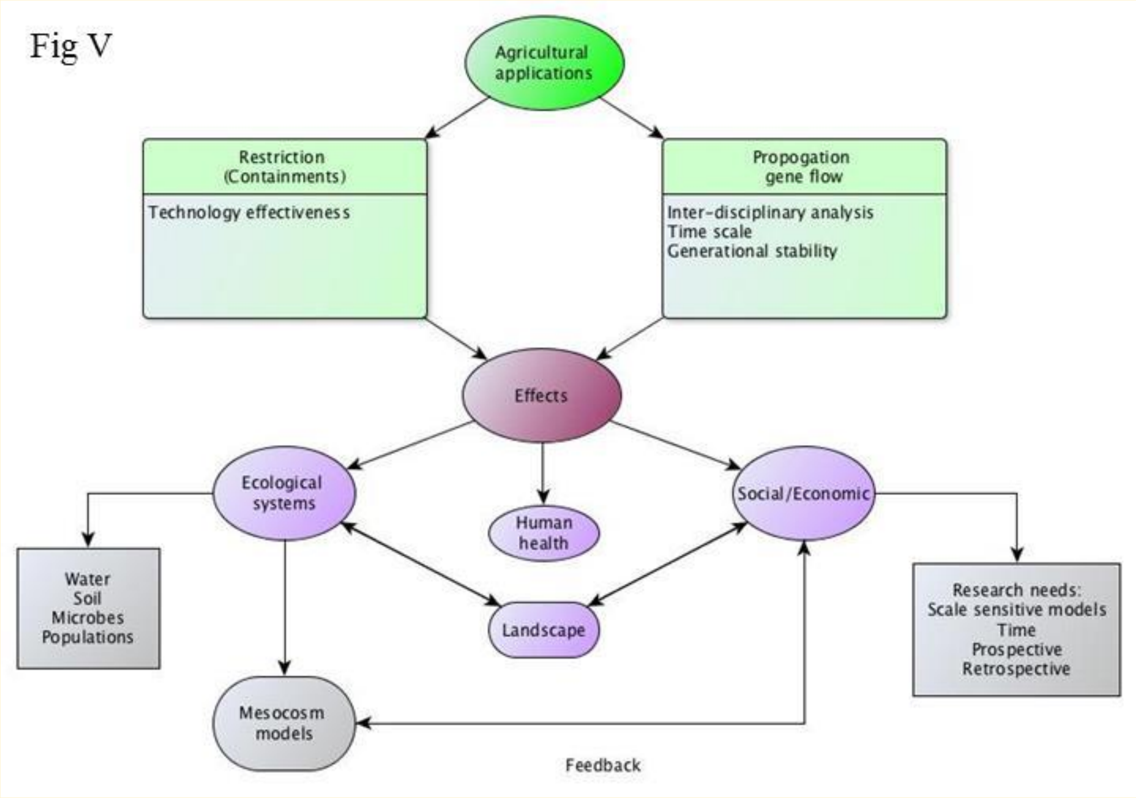
The group also discussed human health impacts of this case study, both positive and negative, including- food security, better environmental quality, and potential risks associated with ingestion of SynBio organisms. ***Environmental considerations again included the bio-persistence of engineered micro-organisms in the environment, effects on soil health, impacts on current microbiomes, and gene flow to other bacteria and organisms.*** Discussion led to asking how to integrate these and other data needs into current research processes (see section 4D). Further questions regarded the sophistication of regulatory schemes for diverse and complex outcomes, and many were concerned with issues of assessment of SynBio *in situ* as opposed to in more artificial or controlled environments. Lastly, the group raised questions regarding the ownership of intellectual property for this technology, and what costs will arise regarding distribution of the technology to less fortunate populations (Fig. IV).

Fig IV



E. General Agriculture

This group was tasked with discussing SynBio applications more generally for the domain of agricultural applications. The group took ***this broader frame in terms of environmental benefits and guardianship over who is responsible for risk management and who is likely to profit from SynBio agricultural applications.*** Issues arose regarding the expected benefits that gene drive technology development in this field, as well as issues concerning gene flow, horizontal gene transfer, and containment. For agricultural applications, SynBio is starting with a longer history associated with genetically engineered foods that was affected by mismatch between the profiteers (companies and farmers) and the ones who directly bore any risk (consumers). Other group members discussed issues of gene stability and functionality over time. All group members agreed that organism physical or biocontainment must be improved for the regulatory structure to be effective in pre-release decisions and post-release monitoring and compliance. Some group members also questioned the viability of previous research models to adequately provide data suitable for decision-making concerning agricultural risks of SynBio applications. The group also ***prioritized needs for future data collection concerning pest management, governance over containment and undesired gene flow, and R&D evaluations on which technologies to fund*** (Figure V).



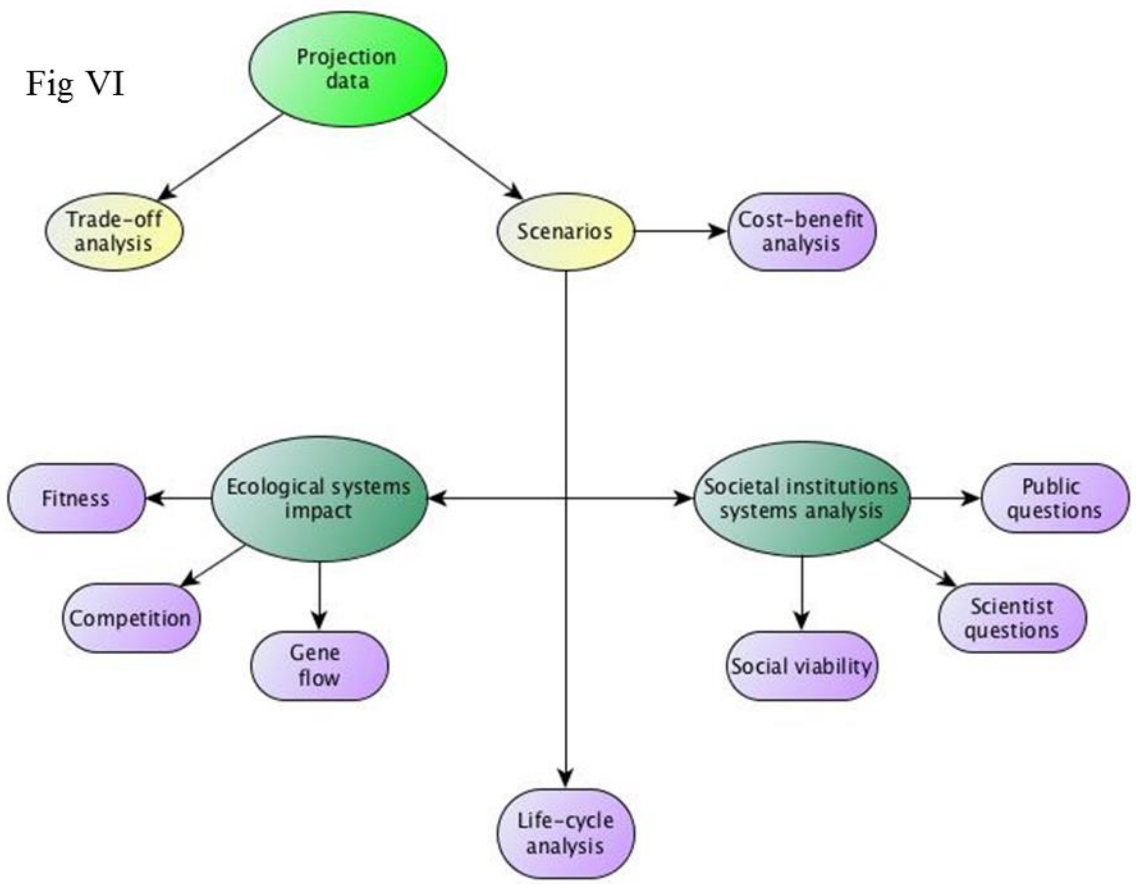
The use of ***mesocosm experiments was given importance, along with prospective and retrospective modeling that takes into account time and geographic scale, and interdisciplinary evaluation with socioeconomic concerns***. This map was highly integrative of social, economic, and risk-benefit issues.

F. General Non-Agriculture

This specialty group was tasked with discussing general SynBio applications being developed for environmental purposes that are non-agricultural in nature, such as bioremediation, human pest control, bioenergy, conservation, or other applications.

Participants noted that a dearth of data exists in the deployment of organisms in ecosystem contexts and further inquiry involving field trial data, historical data, ecological systems and society, and economic impact assessment should be undertaken to improve future governance plans (Fig. VI).

Fig VI



Life cycle and trade-off analysis were discussed extensively. An analysis of the ***costs or risks of not deploying the technology versus the costs or risks of deployment were seen as very important*** for decision making. It was agreed that cradle to grave assessments, looking at every step in the deployment cycle, would be important for environmental use. However, questions were raised about whether there would be an end to such assessments given that some subset of the organisms deployed would persist and given that wider system effects may be seen. It was suggested that ***projections be made 10 to 20 years out into the future and scenarios be drafted to begin these broader analyses***. Fitness, competition, and gene flow were deemed as key natural science questions for the ecological impacts of these scenarios.

This group had extensive discussions about societal institutions and social viability of SynBio projects. Such analyses were suggested as part of scenario development and could be based upon broader engagement that would collect scientists' and public questions. Much of the discussion concerned needs for improved public engagement. This group felt it necessary to know the concerns of the public, and to find intersections between publics and experts. Some questioned the timing of when the public would fit best into the research and development process. Participants questioned ***what kinds of processes will engage the public and what sorts of information might improve public trust***. The group noted a lack of current understanding regarding societal trust in oversight and institutions for SynBio. The idea of integrating the public into the research process rather than separating them with field trials and buffer zones was posed.

Finally, the group discussed a principle-based floor of best practices which should be widely accepted, well-articulated, and must endure shared benefits and risks. The group thought that this goal would also instantiate meaningful mechanisms to bring together oversight institutions.

G. **Summary of Data and Information Needs**

In general, although the groups raised different points for each case study, they all broadened the scope of what is currently considered in regulatory review. Life-cycle assessment, trade-off analysis, problem formulation and comparison of technological or non-technological options for problem solutions, integration of socioeconomic considerations, and public engagement were featured in the concept maps for data and information needs. Because of statutes and regulatory review constraints, often these are not a part of formal oversight. The exception might be environmental impact statements (EIS) occurring under the National Environmental Policy Act (NEPA), which comes into play only for actions the agencies deem significant. Often regulatory review for GMOs does not result in the full EIS process (e.g. Kuzma 2014). Cost-benefit analysis and risks of not deploying the technologies were also seen as important for assessment.

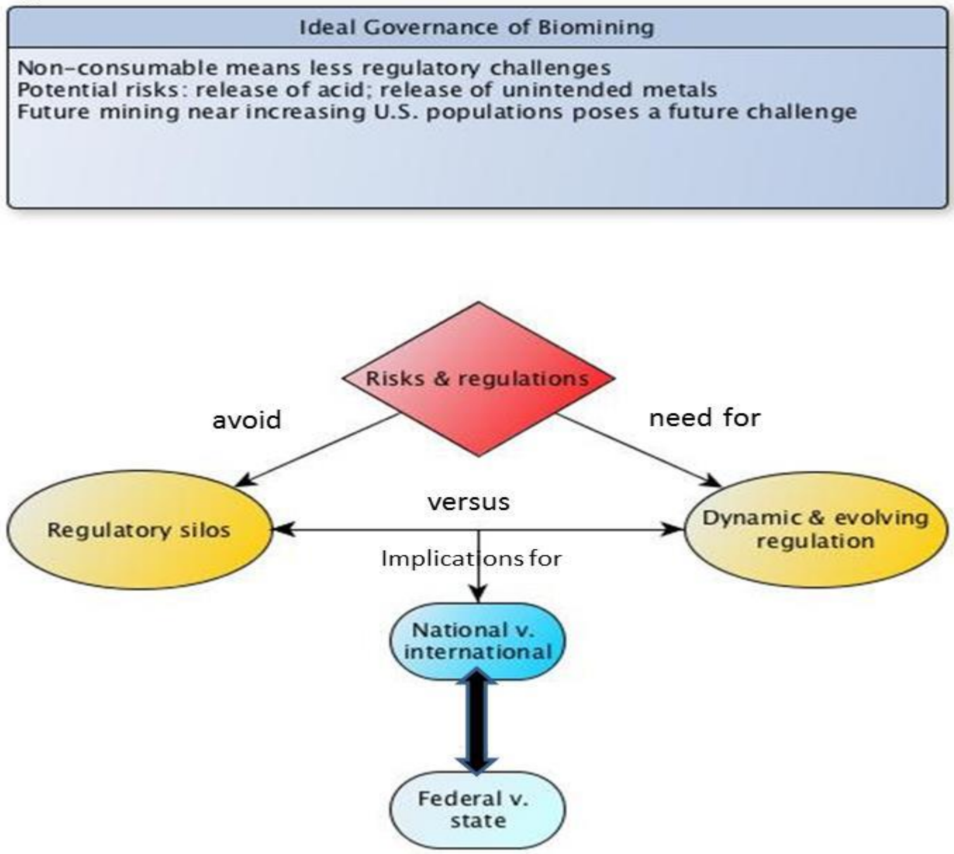
4. What would an ideal governance system look like?

After discussing data and information needs, the same subgroups were asked to identify what components and processes there should be in an ideal governance system. The cases provided an anchor to engage with specific ideas, but participants did not limit ideas for governance to the cases. Groups highlighted both conflicts and opportunities that we are likely to face when envisioning ideal governance conditions. Each group was tasked with creating mind maps of challenges and opportunities:

A. Biomining & Governance

Key criterion for governance identified by this group included flexibility, adaptability, and predictability. The group discussed current regulatory silos and other constraints, such as the inability to include benefits in some agency review processes that might get in the way of systems that are dynamic and can evolve with the technologies that develop (Figure VII). They also noted ***the tension between shared responsibilities of developers, scientists, and regulators, yet the need for product liability.*** There was some disagreement between those in the group that thought biomining using SynBio would be comparatively less or more of concern from a risk perspective. Arguments for more concern included the potential for the release of non-desirable metals from soils and the historical lack of trust in the mining industry, whereas some viewed a lower relative risk due to site-specific releases, inabilities of the microbes to thrive away from the targeted mining sites, and the fact that the SynBio products for mining are not destined for consumption (therefore low exposures). Other important features of the groups mind map include the ***need for integration at geographic scales, as several local, state, national, and international land regulations exist***. This scale-integration presents additional reasons for coordinated approaches that transcend silos, but also presents challenges in wide coordination to make a system dynamic and adaptive.

Fig VII

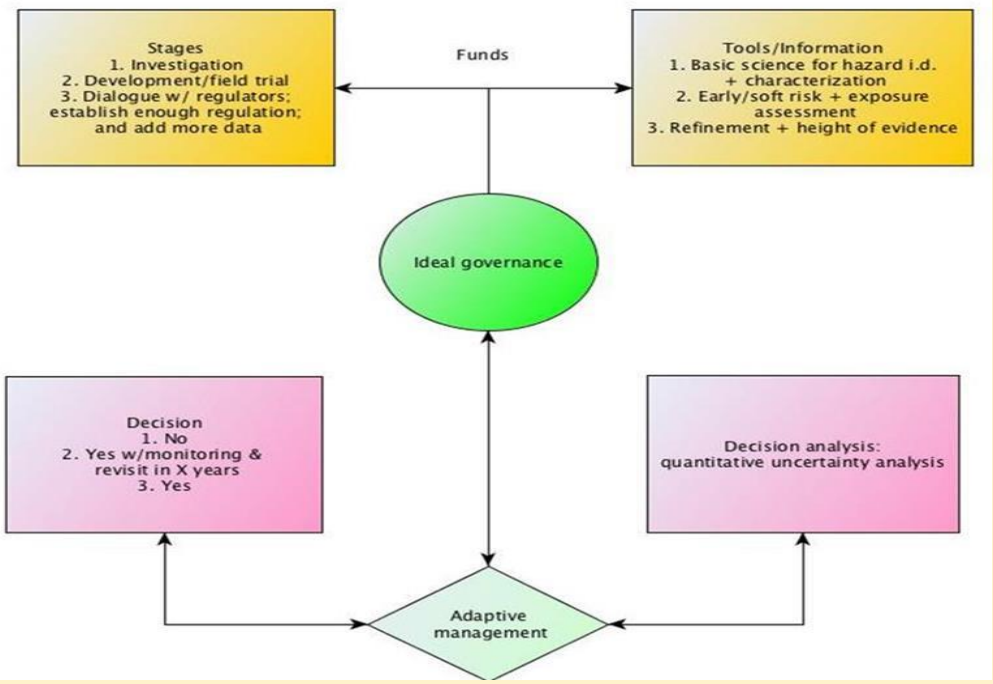


B. Cyberplasm & Governance

The Cyberplasm group suggested a staged model of risk management with roles for different stakeholder groups (Figure VIII): investigational, development & field testing, formal regulatory review, and decision & deployment. Risk managers are in consultation with scientists and developers throughout these stages and the media takes a role at any time, but especially during the final stage, in reporting the work to others. Politicians and the public should have important roles to guide and inform the work at the first and third stage, albeit in practice this is not always the case. The tendency is for the public to only react to what is decided post regulatory review as there is a lack of opportunities elsewhere. The group noted that this is not ideal, although some thought public engagement would be very difficult and costly in early stages of the work. ***Key***

criterion that were stressed included "weight of evidence" approaches, incentives for small companies and developers to engage with the regulatory framework, and tiered review whereby there are additional choices other than full release or denial. Conditional approvals were noted as an important choice that doesn't exist for some products under existing biotechnology regulations under the Coordinated Framework for the Regulation of Biotechnology (CFRB). ***A societal need for a "fair witness" was expressed—one that can conduct assessments and evaluate outside of conflicted parties***. There was also discussion about the media and role of science fiction and concern expressed about how public narratives can get out of control, which is a public risk especially for this case study. Cyberplasm might be viewed as another *Jurassic Park* or robots out of control application, and communication about the case was seen as a crucial part of government.

Fig VIII



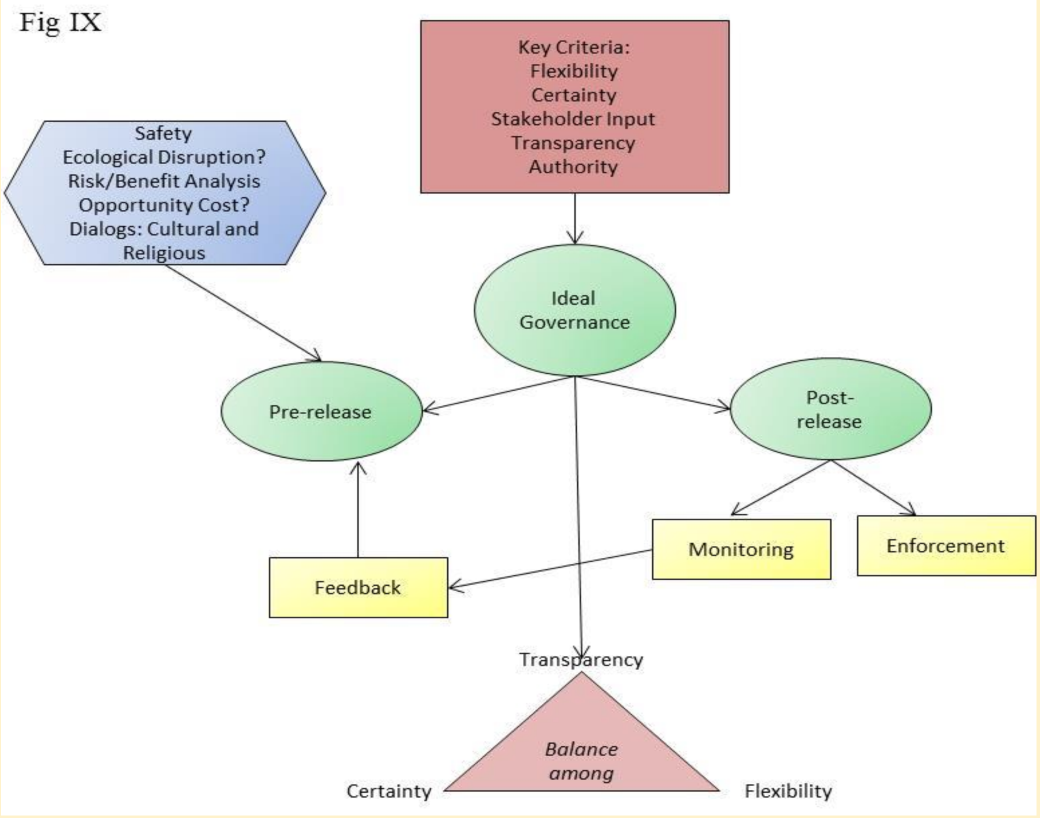
C. Deextinction & Governance

The group highlighted the need for ***ideal governance to begin with efforts to obtain stakeholder buy-in.*** Stakeholders that the group identified included bench scientists, industry, DIY Bio, general public(s) representatives, government, investors, conservationists, and environmentalists. Other key elements of flexibility, regulatory certainty, transparency, and sufficient legal authority were noted (Fig IX). The group suggested ***an iterative process of post-release monitoring, compliance and evaluation that would in turn feedback into improving the assessment process***. Notably, given the potential societal concern and ecological consequences, the group suggested

dialogs around cultural and religious values as key part of analysis prior to any release. One limitation of such upstream processes is the lack of transparency about who is investing in deextinction projects. Achieving a balance among transparency, flexibility, and regulatory certainty was viewed as a particularly difficult challenge for de

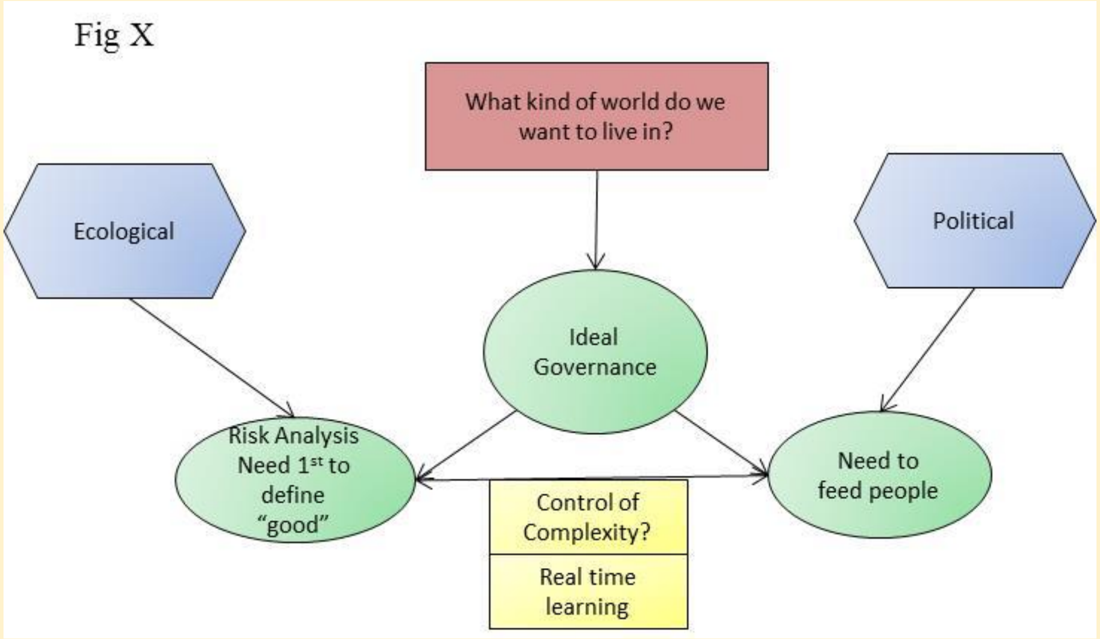
extinction. Because of the novelty of SynBio used for deextinction and the inability to control some species once released, the group suggested that ***this case may warrant a special level of regulation and should not be left to market driven processes***. Decisions to release organisms may be morally attractive to ameliorate human-caused extinction, but a significant level of uncertainty would need to be tolerated as the unknowns are great.

Fig IX



D. Plant Microbes, Nitrogen Fixation & Governance

An important part of governance for this group was to ask broader questions of the societal need for SynBio microbes in N fixation and the public good that may or may not result from the application. ***Comparison with alternative approaches was a key starting point for ideal governance along with potential benefits that may result from the use of SynBio*** (Fig X). ***Feedback loops in decision making, adaptive governance, and real time learning in social institutions were stressed as important.*** For this group, it was important to define the public goods such as the goal to feed a growing population. The group questioned whether regulation in general was designed for complex systems. The idea to provide financial incentives for developers to integrate such broader questions and engagement processes into research and development was raised. The map the group drafted for ***governance starts with the question of what kind of world do we want to live in?*** The group suggested ***predictive systems models*** as important for assessment and decision making.



E. General Agricultural Applications & Governance

This group developed a stakeholder map to suggest where in the process different types of stakeholders have input (Figure XI). Concepts such as ***ethics training for do-it-yourself synthetic biologists, government consultation with bioethics commissions (not typically done for agricultural technology), and ethics in standard development*** were raised. For ideal governance, the group suggested ***principles and processes such as transparency in development, feedback and monitoring, stakeholder analysis, case-by-case review, liability assessment prior to market, and prizes or competitions to incentivize the governance process.*** Lowering barriers to the flow of progress (peristalsis) were thought important (Figure XII)**.**

Fig XI

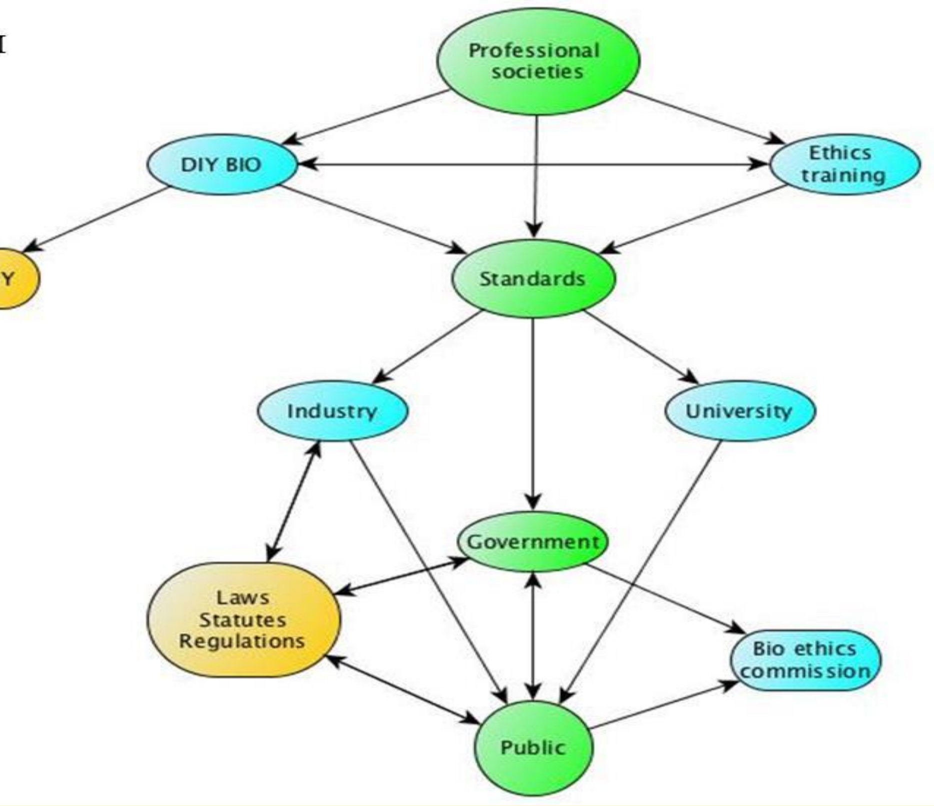
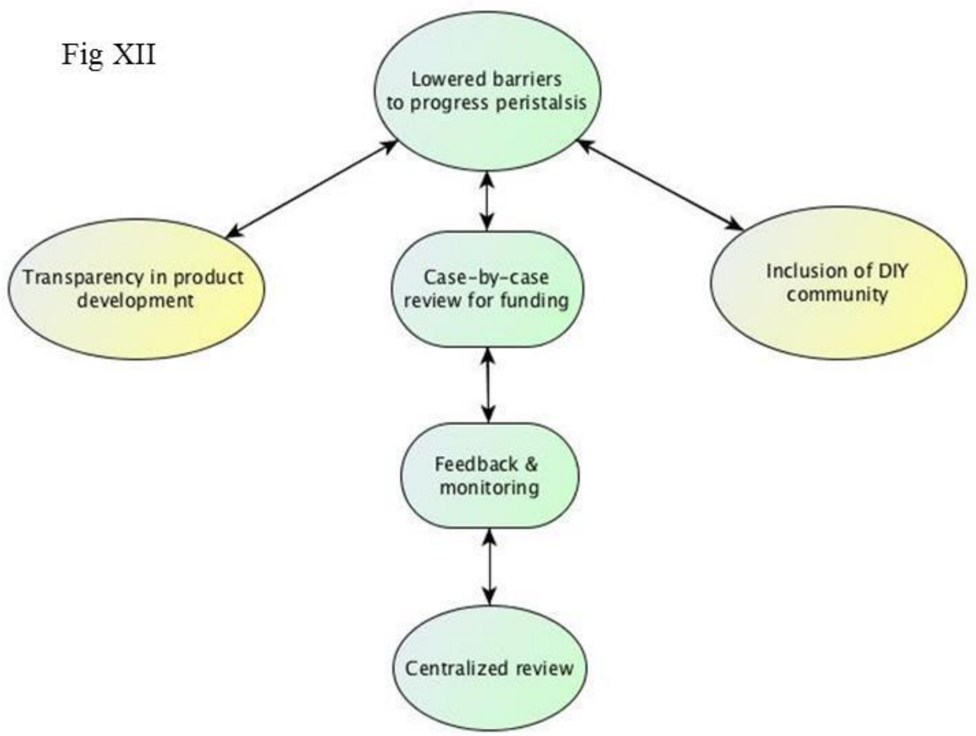


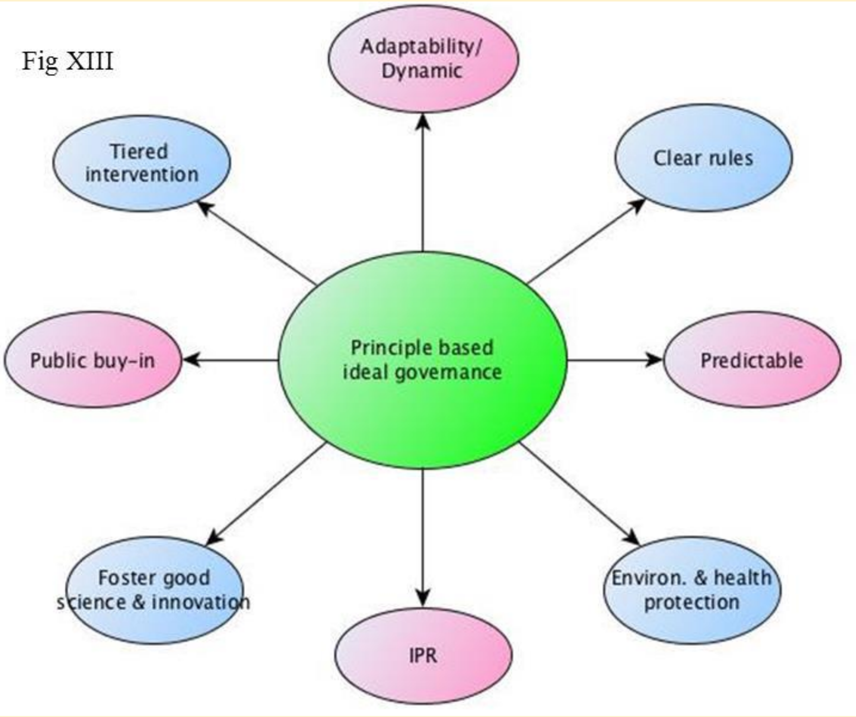
Fig XII



F. General Non-Agricultural Applications & Governance

The general environmental applications group stressed ***the concept of a "ceiling of acceptable behavior" as a principle of governance, one that requires a strong community that can implement codes of conduct***. The system should be based on principles that are well-articulated and accepted with characteristics that foster innovation. The ***DIY community was seen as a positive example of being able to agree upon codes of conduct and develop standards***, as economic motives are not usually present. DIY labs were suggested as a testbed for this system. In addition to the principles identified in Figure XIII, ***institutional review boards, animal care committees, and ethics training were also noted as key components of governance***. ***Trustworthiness, international harmonization, shared risks and benefits among stakeholders and publics, and increasing our abilities for foresight to help assess where we will be in the future were also key elements emerging from the group.***

Fig XIII



G. Other Cross-Cutting Themes

All groups discussed the possibility of ***needing new governance approaches versus simply tweaking existing regulations, especially for the cases further out into the future without natural analogs*** (e.g. Cyberplasm and deextinction). In many cases, there could be multiple agencies involved with governance, thereby creating multiple layers of institutional complexity. Biological complexity of SynBio was seen as a particular challenge along with the associated uncertainty. Some thought that a solid definition of SynBio would be needed for governance; while others pointed out that we have regulated many technological domains with varying or imprecise definitions.

A debated question was whether there should be a difference in governance when comparing natural, GMOs, and more synthetic organisms. Many groups discussed using the ***CFRB as a starting point for SynBio governance, but most saw it as inadequate from a broader systems perspective and for adaptive and dynamic governance.*** Engaging multiple groups and discussions of core values have not traditionally been part of the CFRB process. Barriers to transparency and information flow in product development, due to intellectual property and especially confidential business information was seen as a major complication as it has been for some GM products.

In discussing what is important for governance, ***expert and non-expert heuristics become increasingly important.*** Questions regarding how these technologies fit into a broader societal context were seen as paramount to their success or failure, but people are not likely to agree on the role of technology in society, and group members often disagreed in the conversations. ***Differing ethical and economic motivations will play a significant role in conflicts***, and these are not often brought to the forefront in current governance regimes.

The groups agreed that the role of governance is to ***protect the public and environment from harm***. With that being said, what role do the various governmental agencies have, and how does that fit into the current system? There could be a complementary system where the regulatory system would also consider the pedigree of innovation and in which ***governance should be approached from a collaborative design processes*** versus individual downstream review processes.

All groups thought that it was important for ***governance to be flexible, adaptable, and predictive***, ***with feedback loops from prior experiences and releases.*** Conditional approvals and tier-like interventions based on the level of uncertainty should be considered for new SynBio applications. Governance tiers could be determined initially from a weight of evidence approach, predictive models from experience with natural analogs, and stakeholder assessments of the concerns and benefits. Once applications are released, there should be ***continual monitoring for any environmental or health disruption***, as well as evolution of the organisms released, and there should be feedback loops to inform and change the governance or regulatory approach in real-time.

Principals and processes were seen as cornerstones of ideal governance. Principles can ensure a fair distribution of benefits and risks, while underlying a s***afety-by-design proces***s. Since different applications will trigger different responses, it is ***critical to have meaningful engagement and buy-in from many different stakeholders.*** Transparency, credibility, and frequent communication were seen as essential in gaining trust and increasing the ability to convey factual information.

5. Challenges and Opportunities for Ideal Governance:

After considering elements and systems for ideal governance, the participants were asked to identify barriers that may prevent and opportunities that may facilitate its realization. Each participant was asked to write barriers and opportunities down on note cards, and then the cards were organized by the group into larger categories. They were then asked to vote on those deemed most important to facilitating appropriate governance for all the cases and SynBio as a whole (Figure XIV).

Fig XIV

The categories contain examples of both challenges and opportunities with the total sum of both presented in Table I. The barriers deemed most important by the group centered on lack of public trust, insufficient scientific and public understanding, and the inflexibility of current regulatory models. However, the participants identified and voted on more opportunities than challenges and expressed several novel options for governance. More information on the content of these categories are described below.

Table I

Category	Total Votes	Comments
Standardization	7	Opportunity to develop standards as a SB community
Existing Systems	9	Opportunity with caveat that existing systems will need change
Sustainable Technology	14	Opportunity for sustained communities of ideal governance practice with caveat of difficulty funding
Innovation in Governance	12	Opportunity with scholarly models of innovation and new generations of scientists
New Stakeholders	3	Opportunity with new, young developers of products serving governance
Improved Futures	3	Opportunity for changing metaphors and improving futures
Regulation	10	Opportunity to harmonize , coordinate and reopen discussion of current system
Risks and Benefits	14	Opportunity to fund risk research, incorporate safety in design, and consider benefits.
Ethics	10	Opportunity to develop codes of conduct, practices, and discussion.
Engagement	11	Opportunity to engage stakeholders, practitioners, and the young through iGEM competition
Definition	5	Opportunity for flexible defintiion and learning from bio- and nano-technology
Training	4	Split between opportunity for co-training of engineers/biologists (2) and deficits of iGEM model (2)
Funding	25	Split between opportunity (18) for new incentives for governance and challenge (7) to secure resources
Understanding/Comprehension	20	Challenge with lack of knowledge of synbio, prior experience, uncertainty, etc.
The Social	9	Challenge due to tension between market versus public driven models that impede public input
Uncertainty	3	Challenge for making product approvals
Control	2	Challenge for better governance due to power in hands of a few and negative view of regulation
Trust/Fears	19	Challenge due to public anxiety, lack of trust, and fear of unknown
Regulatory Adaptability	27	Challenge of static, inflexible systems with few feedback loops or preparation for new products
Terminology	5	Challenge of lack of standard definition and boundaries of what synbio is and isn't
Transparency (CBI)	3	Challenge due to current policies on CBI and disincentives for sharing information
Coordination	12	Challenge with static laws, lack of spaces to coordinate, and additional system structures
Risk Assessment	10	Challenge of never enough information for decisions

***Standardization*:** Standards development is a nascent field of study and offers a potential opportunity for the redesign of governance systems. Pre-competitive cooperation on developing measurement standards for assessment would be advantageous. Funding could be refined to incentivize standardization of biological parts, and to tie risk assessment to a given component or circuit. Group members noted that leaders in the SynBio community have the opportunity to serve by pioneering responsible development.

Existing Systems: Many participants noted that it is still very important to work within the existing governance systems, while addressing and filling in gaps. There is the opportunity here for using our experience with other novel technologies so that we don't "reinvent the wheel" concerning governance approaches. However, members also agreed that existing systems should be adapted with other conceptual bio-based technologies in mind for future governance needs.

***Sustainable Technology and Governance*:** Group members commonly addressed the need for refined descriptions of the scope of SynBio applications. There should be no commercialization of products in the absence of relevant, specific regulations. Intellectual property could be realigned to better incentivize commercialization of applications that relate to the global "Grand Challenges." Members also put precedent on developing sustainable technologies and building governance systems that sustain opportunities to compare technological options and maintain diversity. Some noted that opportunities exist to develop annual meetings between academic, government, industry and other interested groups to determine current technology and potential monitoring and regulatory issues in order to keep up with the speed of science and technology development. Further opportunities to develop decision support tools for comparative evaluation of risks across multiple criteria are also possible. There is also potential for the strategic use of "convening authority" of executive governmental agencies to coordinate research and review concepts in light of 21st century science/technology advancements. Lastly, participants noted that grand challenges exist in finding resources to support new governance systems; who will pay? And who will be responsible?

***Innovative Governance*:** Broadening the scope of governance received high votes among participants. Some group members noted that the next generation of scientists and engineers are interested in developing larger frameworks for creatively and collaboratively finding solutions to sticky problems. Some participants urged that we develop decision support technologies for comparative evaluation across multiple criterion and meters. Participants also suggested the opportunity to harmonize governance globally for SynBio, given its early product development stages. Such new governance frameworks would require international buy-in and inter-institutional buy-in to be effective.

***New Stakeholders*:** Related to some of the opportunities mentioned above includes a younger and more idealistic research community in SynBio that has desires to contemplate ethical, legal and social issues and solutions.

***Improved Futures*:** Many participants recognize that as a field SynBio will evolve over time and will likely contribute to improved futures in diverse areas. They noted that SynBio still holds a promissory tone and that applications will need to have large societal impacts to shift the valence from expectations to true beneficial realities.

Funding: Participants proposed the idea for an X-prize in governance, which received strong support. Members thought that such a prize would promote future dialogues about governance within the scientific community. Other members thought that there are opportunities to develop line item funding for SynBio in terms of science, governance, social science, et cetera. They noted however, that many common funding agencies (NSF, USDA, EPA) have little money devoted for such enterprises and that new funding models are needed to improve cross-disciplinary studies. Lastly, new funding models should be explored to incentivize standardization of biological parts.

Regulation: Many issues were raised concerning existing and needed regulation. Some thought that there needs to be improved focus of policy makers on updating regulations concerning GMOs (note: a memo to do this was published by OSTP July 2, 2015). Others noted the problem that the pace of regulatory approval is much slower than the fast-moving pace of scientific and technological development. Some members said that now there are opportunities for the US regulatory system to open discussion on changing regulatory frameworks. Members also noted an opportunity to build consensus internationally on risk assessment models and to improve cooperation and collaboration across regulatory bodies. Expanding review teams for the funding of SynBio projects to include attention to risk analysis, life cycle assessment, and governance approaches was thought to be another potential opportunity.

Risks and Benefits**:** Group members urged for the development of new models for ecological risk assessment. Specifically they articulated a need for improved funding of research for quantitative models that can provide risk assessment for SynBio applications meant for environmental release. This may better match understandings of risk with future regulation.

Ethics: Members also urged for increased transparency concerning health and environmental effects and the adoption of a more precautionary approach to risk management for truly novel SynBio applications (e.g. deextinction). Participants noted opportunities including the following: social engineering of responsible behavior; teach, build, and discuss responsible behavior in non-traditional practitioner communities (e.g. DIY Biology); create routes to develop and propagate ethics and practices (professional societies, funding agencies, IGEM, et cetera.); and contribute to robust and ongoing discussion about codes of conduct/responsibilities and ethics (could tie in with an annual meeting).

Engagement: Participants noted that iGEM is a public face of SynBio, representing a new type of scientist – an interdisciplinary, societally responsive, trustworthy personality. "Design" talk unites different communities, working at different scales that can serve as platforms for engagement, or "co-design". The international participatory nature of such events may be a locus for developing international governance frameworks. These events may also serve as sites to engage public and stakeholders early in the development process.

Understanding/Comprehension**:** Challenges were abundant in this category. Members note that there is disagreement about what SynBio is and what it includes, as well as who is actually doing SynBio research (academics, industry, DIY, international, etc.) They also question which stakeholder groups are at the greatest risks of exposure from SynBio technologies, and who will reap the benefits of such applications. Further questions were raised about the actual characteristics of the DIY community. Additionally, barriers exist due to lack of evaluation frameworks, and there are pressing needs for new methods to assess persistence of engineered organisms in natural environments.

Training: Some members noted that professional training must be improved. Some suggested that academic institutions should improve cross-disciplinary education where engineers receive training to think like biologists, and vice versa. Further opinions were expressed over concerns that events like the iGEM competition promote "quick and dirty" research that is myopic, overly tech-optimistic, and may tarnish future generations of young scientists by presuming that societies problems can be solved both quickly and purely through technological means.

Social/Societal: Some group participants noted a severe lack of social and political factors being accounted for in current governance processes. They noted that mechanisms for soliciting stakeholder feedback throughout the research design and development process could improve governance and even technological development. Some noted that "design" of organisms is antithetical to evolution; a problem not only for engineered organisms but also one of the technological issues in science and society. Tension exists between science and technology being investigator-driven versus societal input into how science should be done and which applications should be prioritized. Most participants agreed that opportunities abound for development of public outreach and education initiatives in the US, which is one of the least scientifically literate countries in the developed world.

Control: Some workshop participants noted the tensions regarding power and control over governance systems. They noted that some groups and industries desire less governance while others would be in favor of greater oversight. Many participants felt that there is currently an air of resistance from scientists toward regulation and governance in general; they already feel the burden from IRB's, ethics training, et cetera.

Trust/Fears: There seems to be conflation and sensationalism of both the rewards and risks of SynBio, especially as it relates to public perception. Hyperbole and uncertainty seem to dominate many conversations regarding risks and benefits of SynBio. The public speculates on default assumptions about SynBio risks and consequences, coupled with their trust or lack thereof in the government along with the fear of the unknown. There is a tendency to focus on extremely low probability, and unprecedented events rather than more likely occurrences. Most participants agreed that further inquiry into drivers of public opinion should be undertaken.

***Regulatory Adaptability*:** The biggest challenge noted by participants was political gridlock in the US congress, which is preventing a fresh and rational look at the US regulatory system for Genetic Engineering and SynBio. Some questioned the extent to which existing laws and regulations should be applied or stretched to fit SynBio issues. One expert commented that capacity is an issue, and it is too much to ask for a paradigm shift. Additionally, it was also noted that if laws were written more loosely, then there would be room for flexibility. Having regulators applying or force-fitting within existing regulatory frameworks hinders programs and creates a defacto moratorium. SynBio can potentially enable genetic manipulation not covered by current regulations. As such, national systems of regulation and governance should be closely examined. Members noted that there also needs to be a re-evaluation of the incentives and problems with intellectual property law. Initially regulations were developed for oversight of corporations, not individuals, therefore creating difficulty and over-regulating accessible or dispersed small-footprint technologies. This may change given the rise of DIY Bio.

Risk Assessment: Worker safety needs to be part of regulatory review. Regulations seem to be based on methods of engineering rather than risks. Reducing everything to no measurable risk is a major problem and lack of consensus on risks may require greater regulatory oversight. SynBio is an emerging field and there will never be enough information for traditional risk assessment and management. Both economic risks and benefits also need to be considered.

6. Additional Risk Analysis and Governance Themes

For the final session of the workshop, the group met in large, open discussion. In the large group discussion, the conversations of the day were summarized into some key considerations for governance (Table II). The preparation for failures was somewhat new to the group and discussed extensively. Some pointed out that invariably there will be mishaps and unexpected outcomes and that preparation plans for these scenarios are important to incorporate into risk governance.

Two general problems with governing SynBio were also stressed; one being that it is too amorphous of a set of technologies applied to many sectors. SynBio products include organisms that (a) have multiple genes engineered into them (e.g. biomining & N-fixing by microbes), (b) contain novel amino acids and base pairs, (c) are composed entirely of engineered biological parts (e.g. Cyberplasm), (d) are made with gene editing from organisms of different but related genomic makeup (e.g. deextinction), (e) have gene drive systems for *in situ* population engineering, and finally, (f) may be entirely artificial in the future. It is hard to "capture" these in any governance system, especially with the different settings of deployment from the fairly contained (e.g. biomining & Cyberplasm) to the highly mobile and dispersed (e.g. plant microbes and deextinction). There was a call to "unpack" SynBio for governance (see also Kuzma & Tanji 2010)

A final dilemma expressed by the group is how to come to a middle-ground between those who tend to have more promotional or precautious values when it comes to emerging technologies. Such viewpoints are not based solely on science, but on approaches to the world. At the workshop, there was a mixture of policy, social, and natural scientists and engineers, as well as a mixture of promotional agency and industry perspectives and more precautious NGO and agency perspectives. Clearly the participants' values played into their views on risk and governance. Through this mixture, however, an interesting set of ideas, criteria, and processes were raised, along with more specific recommendations for analysis, data and information needs. This blend seemed to work well for generating broader conceptual maps and lists. On the other hand, when faced with a specific product decision, they are likely to disagree. How can we handle or balance the considerations in regulatory review specifically? Regardless of this meta-challenge, the group seemed to value listening and learning from other perspectives, and that at least would be a good starting point for incorporation into governance, despite the inability to please everyone with specific decisions.

Table II

Governance Considerations	
Benefits to address global challenges	Ethical motivations of actors
Intellectual property regimes	Education about responsibility
Life cycle assessment	Alternative analysis
Trade off analysis	Coordination of authorities
Projections or predictions over time (decades)	Consumer appeal or resistance
Engaging scientists and non-scientists	Economic competitveness
Mesocosms for modeling	Ensuring & validating containment
Retrospection to learn from past	Forecasting tools
Preparing for failure	Pacing governance with tech development

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Appendix 1: Participants List

Berube, David – Professor, Dept. of Communications; Director, PCOST, North Carolina State University

Bhalerao, Kaustubh – Assoc. Professor, Dept. of Agricultural and Biological engineering, University of Illinois at Urbana-Champaign

Boyle, Patrick – Organism Designer, Ginko BioWorks, Inc

Brown, Zack – Assistant Professor, Dept. of Agricultural & Resource Economics, North Carolina State University

Calvert, Jane – Ph.D., Reader, School of Social and Political Science, University of Edinburgh, UK

Carter, Sarah – Policy Analyst, J. Craig Venter Institute

Cummings, Christopher – Sloan Project Co-PI; Assistant Professor, Wee Kim Wee School of Communication and Information, Nanyang Technological University, Singapore

Dana, Genya – Senior Science Policy Officer, U.S. Department of State

Delborne, Jason – Associate Professor, Dept. of Forestry & Environmental Resources, North Carolina State University

Dilley, Abby (Facilitator) – Vice President of Program Development, RESOLVE

Ducat, Danny – Assistant Professor, Dept. of Biochemistry and Molecular Biology, Michigan State University

Evans, Steve – Scientist, Dow AgroSciences

Frow, Emma – Ph.D., Lecturer, School of Social and Political Science, University of Edinburgh, UK

Gould, Fred – William Neal Reynolds Professor, Dept. of Entomology, North Carolina State University; Co-Director, Genetic Engineering and Society Center

Hanson, Jaydee – Senior Policy Analyst; Director; U.S. Chair, Fellow, Center for Food Safety; International Center Policy for Technology Assessment (ICTA); Nanotechnology Taskforce of the Transatlantic consumers' Dialogue; Institute on Biotechnology and the Human Future

Jaffe, Greg (Esq.) – Director of Biotechnology, Center for Science in the Public Interest

Kane, Sally – Economist; Consultant; President, National Capital Area Chapter of the Society for Risk Analysis

Kelly, Robert – Alcoa Professor; Director, North Carolina State University Biotechnology Program

King, Sheron (Ronni) – Ph.D. Student, Public Administration; GES Research Assistant; NSF-IGERT Fellow, North Carolina State University

Knowles, Lori – Assistant Adjunct Professor; Fellow; Chair, School of Public Health; Health Law Institute, University of Alberta; Board of Directors, Institute of Forest Biotechnology

Koeris, Michael – Founder; Vice President, Business Development and Operations; Sample6; BiotechStart.org (MIT)

Kuiken Todd – Senior Program Associate, Science and Technology Innovation Program, Woodrow Wilson International Center for Scholars

Kuzma, Jennifer – Sloan Project PI; Goodnight-NCGSK Foundation Distinguished Professor, School of Public and International Affairs; Co-Director, Genetic Engineering and Society Center

Linkov, Igor – Research Scientist, US Army Engineer Research and Development Center

Mathews, Debra – Assistant Director, Science Programs for the Johns Hopkins Berman Institute of Bioethics

McClung, Gwendolyn - Microbiologist, Environmental Protection Agency

Medford, June – Professor, Dept. of Biology, Colorado State University

Michener, Joshua – Postdoctoral Fellow, Faculty of Arts and Sciences, Harvard University

Mosier, Nathan – Associate Professor, Dept. of Agricultural and Biological Engineering, Purdue University

Ndoh, Tina – Ph.D. Candidate, Public Administration; GES Research Assistant, North Carolina State University

Nordmann, Alfred – Professor, College of Arts and Sciences, Philosophy, Technical University of Darmstadt

Nwakpuda, Emily - Ph.D. Student, Public Policy, University of North Carolina -,Chapel Hill, Volunteer

Palumbo, Anthony – Division Director, Biosciences Division, Oak Ridge National Lab

Pardo-Guerra, Juan Pablo – Assistant Professor, Dept. of Sociology, London School of Economics & Political Science

Pitts, Elizabeth – Ph.D. Student, Communication; NSF-IGERT Fellow, North Carolina State University

Richardson, Sarah – Distinguished Postdoctoral Fellow, Genomics, Lawrence Berkeley National Lab

Rodemeyer, Michael – Executive Director, Science and Technology Policy Internship Program, School of Engineering and Applied Sciences, University of Virginia

Rudenko, Larisa – Senior Advisor, Biotechnology, Food and Drug Administration

Stauffer, Sharon – Program Assistant, Genetic Engineering and Society Center, North Carolina State University

Vogel, Kathleen – Incoming Associate Professor; Political Science; Director, Science, Technology, and Society Program, North Carolina State University

Williams, Barry – Assistant Professor, Departments of Zoology and Microbiology and Molecular Genetics, Michigan State University

Wynn, Alison – Deputy Director, Genetic Engineering and Society Center, North Carolina State University

Appendix 2: Workshop Agenda

Tuesday, June 3

8:00 – 8:15 a.m. Bus for participants from Hotel to James B Hunt Library, Centennial Campus

8:30 a.m. Registration/Sign in/Breakfast

Setting the Stage (9:00 – 10:00 a.m.)

9:00 a.m. Welcome (J. Kuzma)

- Introductory remarks (GES program/Center) (F. Gould)
- Welcome and Remarks from Vice Chancellor Terri Lomax, NCSU

9:20 a.m. Introductions and Ground rules for Workshop (A. Dilley)

- Self-Introduction of Panelists
- Ground rules

9:45 a.m. Presentation of Results from Rounds 1 & 2 (C. Cummings)

Session I: Risk Analysis & Governance Questions: Research, Data, and Information Needs (10:00 – 1:30 p.m.)

10:00 a.m. Concept mapping exercise for governance and decision-making information needs

- Introduction to influence diagram mapping (JK & AD)

10:15 a.m. Coffee Break

- During break, convene into breakout groups by case study
    - 6 groups of approx. 5 people each – 1 for each case study, 2 application specific (agricultural and non-ag environmental applications)

10:30 a.m. Visual concept mapping of governance research, data and information needs by case study

11:30 a.m. Groups report back

12:00 p.m. Working Lunch – catered in room

- Commonalities among cases? Groups?
- Discrepancies among cases? Groups?

Session II: Envisioning Ideal SB Governance Systems (1:00 – 5:00 p.m.)

1:00 p.m. Introduction to mind mapping (JK & AD)

1:15 p.m. Break

- During break convene into small groups (same 6 application-specific)

1:30 p.m. Mind mapping of ideal governance system for SB products/applications

2:30 p.m. Report back from small groups

3:00 p.m. Coffee Break

3:15 p.m. Cross group comparison

- Commonalities/differences among groups?
- Would these elements change depending on the case study? If so, how?

4:00 p.m. Discussion of elements of ideal governance systems

4:30 p.m. Ordinal ranking of elements of ideal governance systems (CC)

4:45 p.m. Wrap-up

5:15 – 7:30 p.m. Dinner – "The Irregardless Café"

Wednesday, June 4

8:00 – 8:15 a.m. Bus pick up for participants from Hotel to James B Hunt Library on Centennial Campus

8:30 a.m. Breakfast

Recap and Progress (9:00 to 9:30 a.m.)

9:00 a.m. Overview and observations from Day 1 (full group)

Session III: Key Barriers and Opportunities Related to Risk Governance Needs and Ideal Governance Systems (9:30 – 11:30 p.m.)

9:30 a.m. Individual listing of barriers to and opportunities for implementing ideal governance systems (including data collection)

9:45 a.m. Full group discussion of barriers to and opportunities for implementing ideal governance systems

10:45 a.m. Break

Session IV: Open Mic – Moving Forward (11:00 – 12:30 p.m.)

11:00 a.m. What question/idea/point for SynBio governance is most important to you? (Round Robin); What question would you like to see the study address in the final round of the Delphi? (Round Robin)

11:30 a.m. Lunch in room

12:30 p.m. Networking time

1:00 p.m. Bus from Hunt library to airport

3:00 p.m. Final bus from Hunt library to airport

[i] Available at http://www.sloan.org/major-program-areas/recently-completed-programs/synthetic-biology/