Context is Everything: Time Frames, Impacts & Risk Communication in Synthetic Biology Decision Making Processes

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The synthetic biology community is engaged in a multi-decadal process focused on scientific expansion, development of new applications and eventual large-scale implementation of promising methods applicable for diverse uses across wide geographic areas—domestically and internationally.In the public discussions about synthetic biology, proponents have generally focused on how advances in basic science will lead to promising applications and uses for societal benefit, while opponents raise questions about the potential risks, the many uncertainties and unknowns, and concerns about societal impacts and implications in both the short- and long-terms.

Before attempting to identify important research areas associated with the societal aspects of synthetic biology, it will be important to have a realistic overview of the scenarios that may arise at different time frames and under different contexts in the public decision making processes ahead. This involves identifying what institutions and experts are involved at different stages of decision making, what types of applications and uses are anticipated as the field expands, and how risks and impacts are understood, managed and mitigated (from the lab bench, through R&D efforts, to the end-of product life-cycle). It is likewise important to distinguish the perspectives and assumptions of the different people involved in deliberations at particular times —from science and technology experts, to government policy makers, commercial and industry representatives, individuals, and public audiences in all their diversity. Finally, because synthetic biology involves the very nature of life and its deliberate manipulations for human purposes, discussions of research agendas must also include the foundational perspectives of philosophers, ethicists and other humanities disciplines.

All the information outlined above will be needed to design effective communication plans that clearly and accurately explain the risks, impacts, uncertainties and mitigation options, as well as address societal non-scientific concerns. Thus, when planning a long term research agenda for addressing societal concerns and engaging/informing the public, it will be important to acknowledge and clearly articulate:

1) **What <u>specific time frame and context</u> is being addressed**—and what stakeholders, institutions and issues arise at different stages of the overall public decision making process. The road ahead should *not* be viewed as a single decision making process—*rather it involves multiple decisions and processes—with each 'solution' potentially resulting in new or different problems, with different societal concerns at each step.* For the purposes of designing a research agenda, it may be useful to examine (compare and contrast) four representative times in the process. (It is arguable that in first two phases, input from the scientific/technical and legal/policy communities predominate —while societal awareness and opportunities for involvement increase gradually over time —as the applications (or problems) become more individually relevant).

> a. Early stages. From the Asilomar era of early research in genetic engineering in high containment labs; to the Ice Minus era and controversies associated with deliberate outdoor release and pilot projects; through the early sybbio era of R& D (to ~ 2000?). This era involved questions of government funding, applicability of existing laws/institutions;

environmental impact statement; and populations addressing mainly local/regional controversies, at least initially.

b. The current situation: the era of deliberative democracy – which includes discussions of bioethics, adequacy of iaws, regulations andi nstitutional oversight,; concerns about responsible research (biosafety and health), especially at academic institutions; deliberations about potential dual use problems; and growth of DIY-ers, IGEM competitions, commercial ideas and venture funding.

c. NEXT: coming era of commercial scale ups & Industrialization (many new and different issues, laws, institutions, and practitioners—a sequential decision making process). The period of expansion beyond pilot scale R&D to large-scale industrial operations with product-lifecycles, international markets, wide distribution, and concerns about end-of-life disposal etc. (comparable to chemical industry; big-pharma; food-agricultural sectors)

d. ALSO-- Need to focus on representative, potential accident scenarios and time frames—involving many different syn-bio products/uses, institutions, publics and issues involved. No one-size-fits-all approach.

2) **look at specific <u>Risks, impacts, and uncertainties associated with the different time frames and situations-</u>**-where do info gaps & uncertainties exist or will likely remain- especially for industrial and outdoor applications

Compare and contrast the issues for synbio applications/uses under c*ontrolled situations in labs or large commercial facilities*
vs.
Consider how qualitative questions about long term impacts from *deliberate outdoor releases and uses—and associated product life cycle and disposal issue—will impact the public* (similar to questions about GMOs and environmental long term changes?)

3) **Risk Communication needs –** For each time frame or context, determine the different societal information needs; & consider analogue or historical information on how to address them. There is an extensive literature on risk analysis and public decision-making, with relevant research on risk communication, risk-perceptions, foundational values, and public involvement. It may be useful to examine existing research findings on effective and ineffective communications as seen in diverse sci-tech analogues [e.g., chemical industry, oil & gas—fracking; GMOs—over time & in different locations -- US vs European); nuclear industry and applications; and even climate change-- for aspects of gradual emergence of problems and public views about accepting/rejecting expert advice and opinions]

a. Consider adoption of best practices for effective communication and outreach efforts (ex. avoid disseminating info in monologues or enthusiastic 'infomercials" and avoid the Deficit Model of risk communication.)

b. Prepare to discuss risks, mitigation, and remediation options in advance? Who are the 'experts' who can engage in true dialogue at different times? (especially if and when accidents occur (the latter is important because there are few or no equivalents of

environmental impact assessments for advance public discussions and hearings)

c. Gather systematic information on public understanding & views of synbio. Surveys indicate that the public is generally uniformed about synthetic biology. Are there opportunities for research on public understanding, risk perceptions, & values of concern?