

Research to assist and to understand international biodiversity governance

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The UN Convention on Biological Diversity (CBD) is one of the few multilateral agreements to have specifically engaged with synthetic biology. Initially introduced through the CBD's negotiations on biofuels, synthetic biology has been under consideration as a possible "New and Emerging Issue" since 2010.¹ As a framework agreement, the CBD primarily produces "soft law." Its political decision-making body, the Conference of Parties (COP), produces Decisions that are unlikely to establish new legal requirements but can be politically influential, mobilizing and guiding scientists, funding agencies, NGOs, businesses, and national governments. The CBD's two protocols contain binding, 'hard' legal commitments on processes for the transboundary movement of living modified organisms² and on access and benefit sharing of genetic resources.³ Neither protocol specifically addresses synthetic biology, but the CBD Secretariat's analysis identifies that many current synthetic biology techniques likely fall within their scope.

This paper suggests research in two areas: 1) research to assist the CBD's deliberations on synthetic biology; and 2) research on international decision-making processes around synthetic biology. These are based on participant observation of negotiating events, embedded work with the Secretariat, and interviews with involved actors as part of my dissertation research.

1) research for international deliberations on synthetic biology

CBD COP Decision IX/29 establishes seven criteria for identifying "New and Emerging Issues" to be added to the treaty's agenda. Three criteria are highlighted here to indicate research that would respond to the CBD's interests.

New evidence of unexpected and significant impacts on biodiversity: At meetings in June 2014, CBD Parties noted that both the "benefits" and "risks" of synthetic biology for biodiversity are "currently poorly understood" (SBSTTA 18 Recommendation XVIII/7). A responsive research agenda would consider current and anticipated applications of synthetic biology. Most current and near-term commercial applications are engineered micro-organisms for contained use. Research on the biosafety of such micro-organisms could examine industrial and research sites for the rate of survival and reproduction of escaped micro-organisms and the transfer of altered genetic material. Organisms intended for environmental release are broadly anticipated to result from synthetic biology research. As such organisms may present new biosafety concerns, a research agenda for monitoring their environmental impacts should be established while such organisms are still under development. Indirect impacts on biodiversity should be monitored too, such as land-use changes caused by expansion in the quantity or kinds of biomass for feedstock and population changes of wild animals or crops whose harvest has been displaced by products of synthetic biology. Ecologists and environmental scientists are particularly needed in developing this research agenda on impacts.

Evidence of the absence or limited availability of tools to limit or mitigate the negative impacts of the identified issue on the conservation and sustainable use of biodiversity: Based on the CBD Secretariat's overview analysis of international law relevant to synthetic biology, CBD Parties have agreed that a "coherent and comprehensive international framework" to address synthetic biology is

¹ The CBD's 12th Conference of the Parties has just convened (6-17 October 2014). At these negotiations, Parties may finally decide whether to add synthetic biology to the treaty's agenda as a New and Emerging Issue.

² In the context of the Cartagena Protocol on Biosafety (2005), "living modified organisms" (LMOs) are "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" (CPB Article 3(g)).

³ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2010).

lacking, but they disagree on whether such a framework is desirable. In evaluating the international regulatory tools available to respond to synthetic biology, two areas of research may be helpful. First, an expansion of the Secretariat's analysis could be carried out for each area of synthetic biology research. For example, analysis would determine how current international legal obligations would likely apply to the organisms that xenobiologists are aiming to produce. Understanding the potential legal landscape for their research results may influence the goals of synthetic biologists, while their feedback may help treaty bodies identify gaps or inconsistencies in their oversight. Second, risk assessment processes developed for genetically modified organisms should be re-examined as synthetic biology techniques make it possible to develop increasingly complex and novel organisms. The Cartagena Protocol on Biosafety's risk assessment process takes into account the environment which will be exposed to the organism, the characteristics of the organism, and its intended uses. If many donor organisms and/or human-designed parts are used, such a comparative assessment system may not be adequate. Research is needed to identify the limits of current assessment methods and their applicability to near-term and anticipated products of synthetic biology. New methods of assessment may need to be developed in response to synthetic biology.

Magnitude of actual and potential impact of the identified issue on productive sectors and economic well-being as related to the conservation and sustainable use of biodiversity: Synthetic biology is relevant to the CBD not just for its impacts on biodiversity but also its impacts on associated socio-economic considerations. Research on the displacement effects of products of synthetic biology, such as semi-synthetic artemisinin, could help to establish the extent to which displacement is occurring, whose livelihoods are impacted, and the distribution of financial and other benefits from the new products. More broadly, research could track the differential global impacts of the expanding "bioeconomy," in which synthetic biology is expected to play a key role.

These suggested areas of research indicate aspects of synthetic biology relevant to the objectives of the CBD (for additional aspects, please see UNEP/CBD/COP/12/20). I believe that the CBD's considerations would also benefit from an analysis of the uncertainties of synthetic biology's impacts on biodiversity. Some uncertainties may simply be gaps in knowledge, resolved by establishing monitoring and surveillance processes. Others may be a matter of waiting for the release of new applications and then tracking their anticipated impacts. More intractable uncertainties, however, are likely involved as well. Some direct impacts will be difficult to measure - the lag times will be too long, the limits of detection too high to register changes. As discovered with biofuels, tracking indirect impacts such as land-use change leads to wide-ranging results, due to fundamental differences in methodologies and the key assumptions of models. And there will be some impacts that cannot be anticipated, even with modified assessment processes. Thus far, CBD Parties have responded to synthetic biology by calling for gathering more information. More clarity on the nature of what is *not* known - probable timeframes for the resolution of information gaps and identification of the more intractable and indeterminate uncertainties - may help governing bodies identify where political responses to uncertainty are necessary and appropriate.

2) research on international deliberations on synthetic biology

The CBD's deliberations on synthetic biology provide an opportunity to study the decision-making processes of an international environmental body as it grapples with an emerging biotechnology. How is synthetic biology defined by actors, and how is the CBD's scope of engagement determined? How are uncertainties identified and framed? What sources and kinds of knowledge are drawn upon? Whose perspectives are reflected, and through what intermediaries? Such knowledge politics are key in the formation of international policy (Hulme 2012; Jasanoff 2004; Miller 2009; Scoones 2009). Research following the CBD and other governing bodies as they engage with synthetic biology could identify the epistemic foundations of resulting policy, analyzing how power is enacted and democracy performed through the contestations of claims of knowledge.