Assessing the Environmental Impact of Synthetic Biology

Chris Warner & Jed Eberly

U.S. Army Corps of Engineers
Engineering Research and Development Center
Environmental Laboratory
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Problem Statement

Technologies and materials based on synthetic biology (Syn Bio) are currently in development.

Definition: **Syn Bio** is the design and construction of new biological parts, devices, and systems, or the re-design of existing systems.

The environmental impacts associated with these new technologies are unknown.
“Synthetic biology is already being applied to creating biofuels and more robust strains of important crops. Over the next 30 years, synthetic biology has the potential to transform everything from health care to energy production.”

Synthetic biology is one of “20 core trends that are likely to have an impact on society, political dynamics, the global economy, environmental issues, and defense between now and 2045.”

One of 20 emerging trends most likely to generate revolutionary or disruptive change of interest to the Army over the next 30 years.
Applications of Synthetic Biology

Materials
- Commodity Materials
- Specialty Materials

Sensing

Human Oriented
- BW/CW Threat Defense
- Medical & HPM

Enabler ---- Operational Role of Synthetic Biology Application ---- Direct

BW/CW: Biological Weapons/Chemical Weapons; HPM: Human Performance Modification
Factors Impeding Progress

- Technical Challenges
- Small number of facilities to design, prototype, test
- Limited number of model organisms
- Limited access to repositories
- Regulatory and policy concerns

The latter is likely to be the premier challenge for development.
Known Challenges: Classification in Synthetic Biology Technologies

Synthetic Biology

- GMOs
- Gene Drives
- Biosensors
- Gene Drives
- Synthetic Materials
- DNA Origami
- Biofuels
- Cell Free Systems
- Microbial Cell Factories
- Novel Enzymes
- Genetic Barcodes
- Synthetic Chemicals
- Synthetic Materials
- Protocells
- Xenobiology
- Synthetic Materials
- ERDC

Innovative solutions for a safer, better world
Known-Unknowns: Activity, Transferability, Toxicology

1. How do we measure fate and transport?

2. What does transferability mean for a synthetic gene/protein?

3. How can we assess environmental impact?
Unknown- Unknowns: Gene Drives for Disease Eradication

1. How will genetically engineered mosquitoes affect the ecosystem?
2. Is it possible for the Gene Drive to mutate and affect non-target organisms?
How do we decide if Syn Bio Technologies are safe to use/test?

Develop information, guidance and a decision support framework to determine potential environmental impacts of synthetic biology.
SynBio Impacts Overview

- Decision Framework
  - Prevention Based Risk Governance
    - Categorization
    - Tech Benefit Analysis
    - Regulatory & Developer Community
  - Environmental Impact Quantification/Testing
    - General safe practices
    - Cell Free Systems
    - Microbial Systems
    - Eukaryotic Systems
    - Develop Qualitative/Quantitative Methods
    - Modeling
  - Decision Support for Environmental Impact Assessment
    - Decision Tree
    - Website
    - Protocols

- Known Challenges (Identification)
- Known Unknowns (Quantification)
- Unknown-Unknowns (Decision Support)
Identification of what is known and not known (Data Gaps)

Objective: Establish a prevention based risk governance concept for synthetic biology

Categorization
Objective: Characterize state of the art technology, regulatory structure & knowledge gaps

Risk Governance
Approach to identifying and categorizing emerging risk

Risk Based
Risk Assessment
Prevention Based
LCA
MCDA
Cost/Benefit
Planned Synthetic Biology Workshop

- Spring 2017
- DoD, Academic, Industry, and Regulatory participants
- Goals
  - Identify outstanding data gaps in our understanding of the potential environmental impacts of synthetic biology
  - Produce several position papers addressing these data gaps
  - Develop a boarder community to address knowledge gaps
Quantification of Known-Unknown impacts. (Fill in Data Gaps)

**Objective:** Quantify environmental impacts associated with synthetic biology technologies.

**Cell Free Systems**
Understand synthetic biology persistence in environment with simple non-cellular systems

**Genetic Sensors**

**Genetic Barcoding Systems**

**Microbial Systems**
Assess the persistence in the environment of a synthetically derived population, the potential to spread to native organisms and the subsequent impact

**HGT**

**Interactions with other organisms**

**Eukaryotic Systems**
Establish validated mathematical models for the spread, persistence, and mutation of gene drives

**Develop “Modelscapes” for Predicting Outcomes and Risks of Self-propagating Gene Drives**
Objective: Compile resources to help assess the impacts associated with synthetic biology products
Contact Information

Christopher Warner, Ph.D M.B.A.
Email: Christopher.M.Warner@usace.army.mil

Jed Eberly, Ph.D
Email: Jed.O.Eberly@usace.army.mil