Addressing Environmental, Security, and Safety Gaps for Engineering Biology R&D

Christopher A. Wozniak, Ph.D.

Wozniak Biopesticide Consulting, LLC

April 22, 2025

The Role of Regulation in Synthetic Biology

- We are blessed with many promising technologies under the umbrellas of molecular biology, synthetic biology and biological control
- All of these technologies rely upon a functional, science-based regulatory system to move novel products forward
- Despite decades of experience with rDNA-derived products / organisms, the paucity of commercially available GE microbial products for pesticidal, remediation and other environmental purposes is striking
- Synthetic genetic elements and recoded organisms coding for non-canonical amino acids will require a reassessment even when common species are used as a genetic chassis

Coordinated Framework for Biotechnology

- Proposed in 1984 by OSTP and published initially in 1986, updated in 1992 and again in 2017
- “The (1992) update affirmed that Federal oversight should **focus on the characteristics of the product, the environment into which it is being introduced, and the intended use of the product**, rather than the process by which the product is created.” (57 FR 6753)
- Basic three tenets: "(1) **U.S. policy would focus on the product of genetic modification (GM) techniques, not the process itself**, (2) **only regulation grounded in verifiable scientific risks would be tolerated**, and (3) GM products are on a continuum with existing products and, therefore, existing statutes are sufficient to review the products.

Disparate treatment of GE microbes

- **EPA-OPP** – Microbes are permitted to be field tested on up to 10 acres terrestrial / 1-acre aquatic w/o notifying the agency; if rDNA is used to modify the microbe, ANY size release requires a Biotech Notification or Experimental Use Permit under FIFRA
- **EPA-OPPT** – Microbes are only regulated if they contain genetic elements which arose outside of the genus of the recipient
- **EPA-OPP** does not require an assessment of impacts of the released microbe upon native microflora; **EPA-OPPT** does require this non-target impact aspect to be assessed
- **USDA-APHIS** largely focuses on the potential for a plant-pest risk

Obstacles to regulatory reform

- **Loper-Bright / Chevron Deference Supreme Court decision**
  - courts may not defer to an agency interpretation of the law simply because a statute is ambiguous
  - Are statutory definitions in question now?
- **Uncertainty in the Rulemaking process post Chevron**
  - Resource allocation in an absence of certainty / ambiguity
- **Interrelated regulations** make modifications difficult
  - FIFRA, TSCA, CWA, ESA
- **Competing goals / perspectives**
  - Stakeholders, developers, NGOs, etc… varying goals

What changes are needed?

- Decision makers need to be well-versed in the technology they are regulating including potential positive impacts!
- Regulations, rules and policies need to be based in sound science, not just in words, but in practice
- Consideration of a ‘No-Action Alternative’
- Development of a process for appeals of regulatory decisions
- Long-term persistence of GE / synthetic microbes does not equate with and an environmental risk