Industrialization of Biology

EPA’s Oversight of Industrial Chemical Production

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The “Coordinated Framework”

- The Coordinated Framework for the Regulation of Biotechnology (1986) is a set of policy statements organized by the White House Office of Science and Technology Policy and issued by five government units with responsibilities for biotechnology
  - Food and Drug Administration
  - Environmental Protection Agency
  - U.S. Department of Agriculture
  - Occupational Safety and Health Administration
  - National Institutes of Health
What the Coordinated Framework Did

• Acknowledged that existing law was sufficient to permit oversight of biotechnology
• Permitted each agency with oversight responsibility to describe how it implements its regulations in this area
• Established lead (but not exclusive) roles for identified uses of biotechnology
• Recognized that some overlap of authority existed and established coordination among agencies that had overlapping responsibilities.
EPA Has Regulatory Authority Over Synthetic Biology Products Under The Toxic Substances Control Act

- Synthetic Biology is regarded as a form of Biotechnology
- EPA has used TSCA for oversight of new biotechnology since 1986 with formal regulations issued in 1997*
- Synthetic Biology products were included in the EPA Coordinated Framework component that established TSCA authority over some biotechnology products

*Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act
Toxic Substances Control Act (TSCA) and Genetically Engineered Microorganisms

- **TSCA Authority**
  - Under TSCA, EPA has the authority to regulate the manufacture, use, distribution in commerce, and disposal of “chemical substances and mixtures.”
  - Through the Coordinated Framework* policy statement and 1997 Rule, certain microorganisms, were included as substances within this authority
  - TSCA requires premanufacturing notification of all 'new' substances not otherwise excluded or exempted

- **TSCA covers chemical substances (typically used in environmental, industrial, or consumer products) that are not specifically excluded**
  - Substances Specifically Excluded from TSCA Regulation
    - Pesticides, but not pesticide intermediates (EPA/OPP FIFRA)
    - Food, food additives, drugs, cosmetics, and their intermediates, and substances used as medical devices
    - Tobacco and tobacco products
    - Nuclear materials

*Coordinated Framework for Regulation of Biotechnology (OSTP, June 26,1986)
Data Needs for Biotechnology Submissions

“Points to Consider” Guidance Document Elements

- taxonomic descriptions of the recipient and donor microorganisms
- detailed construction of the submission microorganism
- human health effects information on the submission microorganism
- environmental effects information on submission microorganism
- by-products, production volume, and use information
- worker exposure and environmental releases/containment
- environmental release protocols
- expected survival/dispersal - environmental exposures
- emergency/contingency protocols
Types of Synthetic Biology Most Difficult to Assess

• Orthogonal Life – No previous experience / no analogs
• Wholesale Metabolic Engineering that adds complete pathways that were not well studied in the native organism
• Modification of pathways that are not well understood in the recipient organism