

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



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