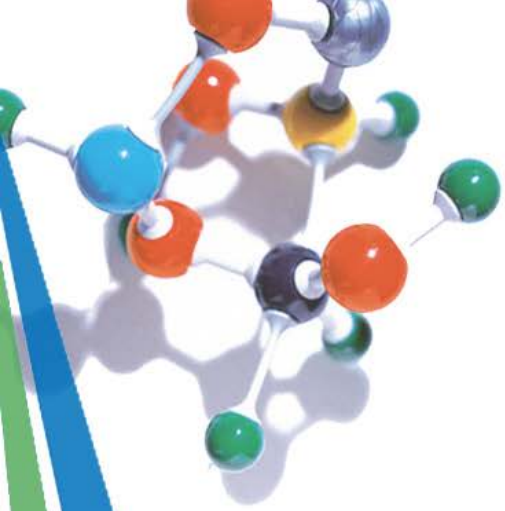
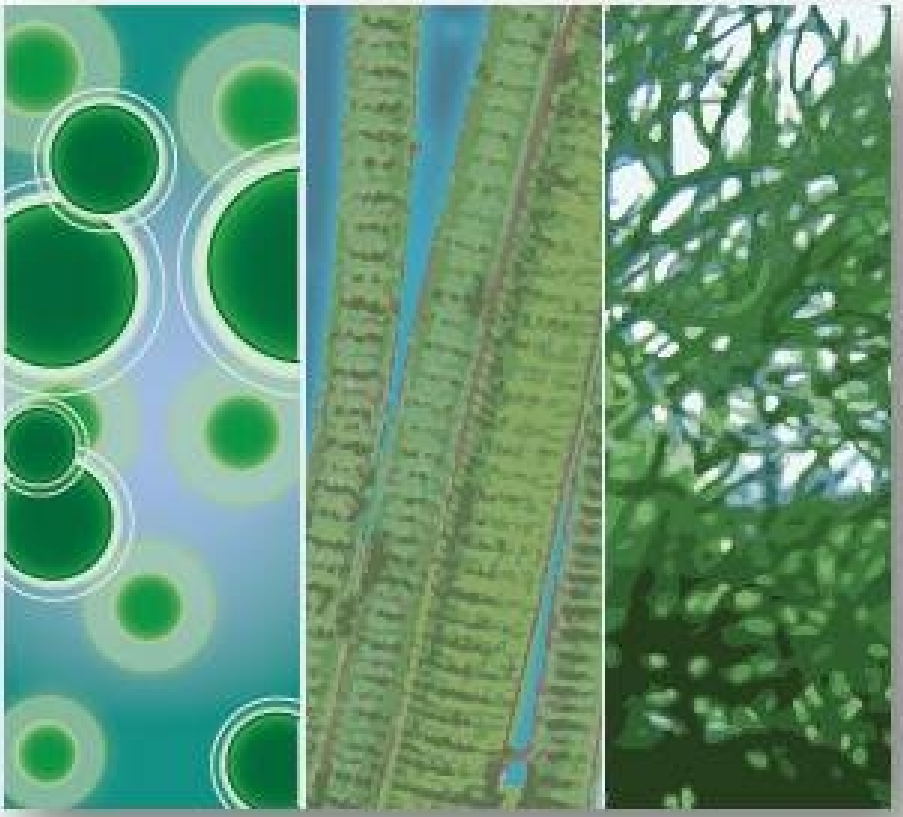


EPA United States Environmental Protection Agency

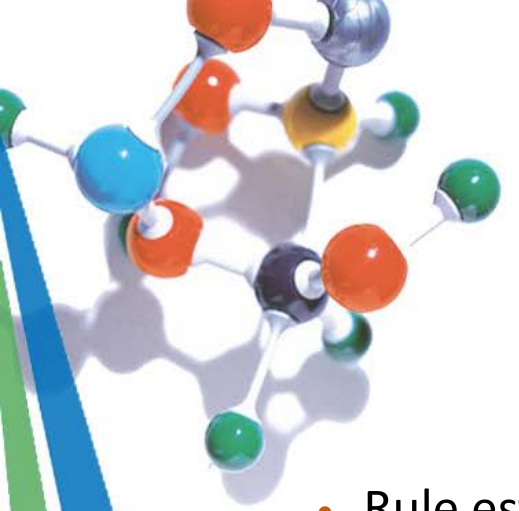
EPA GM/SynBio Algae Guidance Project

27 May 2015

Algae and EPA

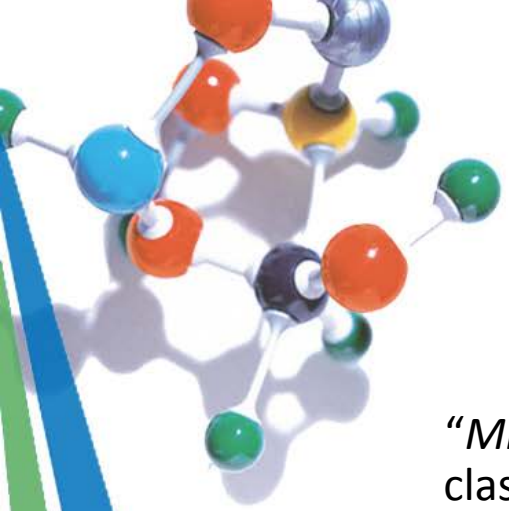


Credit: U.S. Department of Energy



EPA Biotech Rule (1997)

- Rule established procedures for premanufacturing review of "new" microorganisms.
- Rule retained EPA's interpretation of "new" (intergeneric) microorganisms as stated in the 1986 Coordinated Framework Policy Statement.
- For clarity, EPA consolidated all requirements and procedures into one part of the Code of Federal Regulations (40 CFR 725).
- Applies to "new" microorganisms that are manufactured, imported, or processed for commercial activities, including R&D activities.

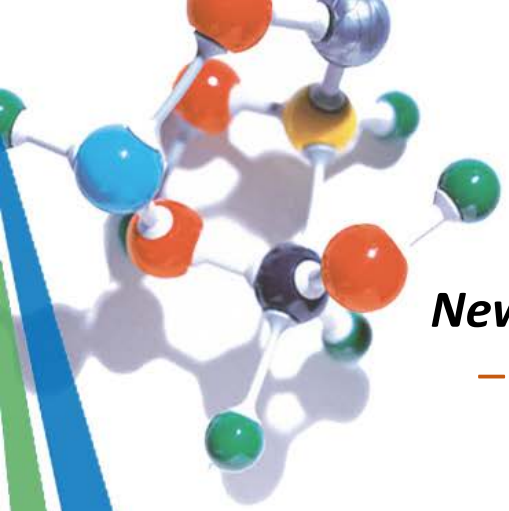


Rule Definition of Microorganism

"*Microorganism* means an organism classified, using the 5-kingdom classification system of Whittacker, in the kingdoms Monera (or Procaryotae), Protista, Fungi, and the Chlorophyta and Rhodophyta of the Plantae, and a virus or virus-like particle."

"Therefore, this definition includes, but is not limited to, bacteria, protozoa, fungi, mycoplasmas, mycoplama-like organisms, spiroplasmas, microphytoplanktons, green and red algae, viruses, and virus-like particles."

"Should new categories of microoganisms within the Monera, Protista, Fungi, and the Chlorophyta and Rhodophyta of the Plantae be identified, these would also be considered microorganisms under this definition."



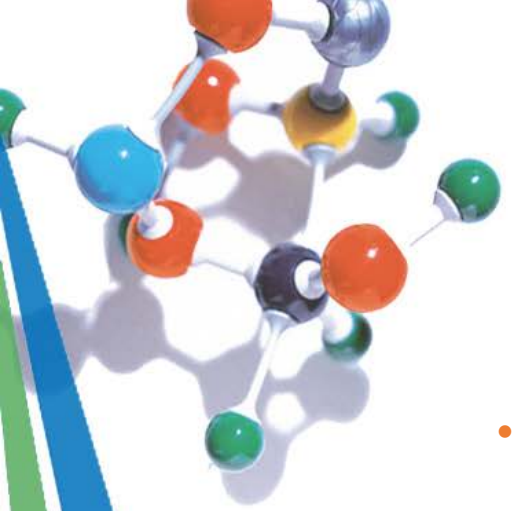
"New" Microorganisms Subject to EPA Review

New microorganisms

- Formed by deliberate combinations of genetic material from organisms classified in different taxonomic genera (intergeneric)
- Constructed with synthetic genes that are not identical to DNA that would be derived from the same genus as the recipient cell
- Not already listed on TSCA Inventory
- Used in TSCA applications

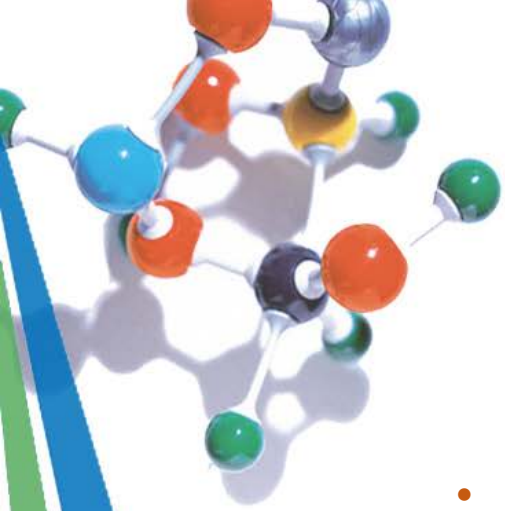
Exclusions

- Naturally occurring microorganisms
- Genetically engineered microorganisms other than intergeneric
- Intergeneric microorganisms resulting only from the addition of well-characterized, non-coding regulatory regions



Data Needs for Algae Submissions

- 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



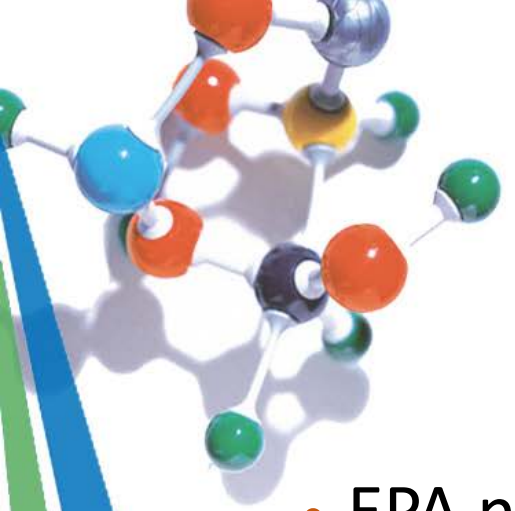
EPA Assessment Components

- Microbial Identification
- Product characterization, genetic construction analysis
- Human Health Hazard Assessment
- Ecological Hazard Assessment
- Construct Hazard Analysis (hazard consequences of genetic construction)
- Engineering Report (worker exposure, releases from facility)
- Exposure Report (environmental and general population exposures)
- Economic Analysis

GM/SynBio Algae Guidance Project

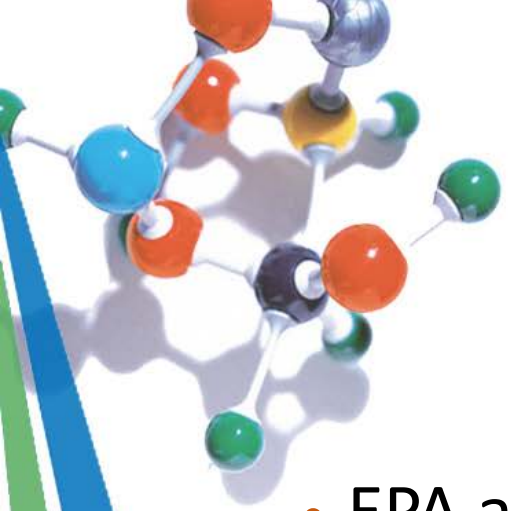
Assumptions

- EPA has GM/SynBio algae information needs for scientific review
- Submitters need guidance for preparing GM/SynBio algae submissions for EPA review.
- The public needs more debate on the introduction of synthetic biology into society.



Leveraging Algae to Advance Broader SynBio Discourse

- EPA needs the guidance, so will be doing it anyway.
- *Synthetic biology* is a broad term, defined several ways.
- Although a narrow case, algae poses many societal questions relevant more broadly to synthetic biology applications.



Next Steps

- EPA aiming to initiate the development of draft GM/SynBio algae guidance this fall.
- Will create venues for public input.
- Can serve as a specific case for broader discourse on synthetic biology implications.