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AFOSR-NREL Microalgal Lipid to Biofuels Workshop

Bloomin' Government! Environmental Laws and Regulations That May Impact Algae Production

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How Could YOU Be Regulated?

- **What are you growing?**
 - TSCA?
 - PPA?
- **Where are you growing it?**
 - Indoors
 - Outdoors
 - What state?
 - What county?
 - Who are your neighbors?

What are you growing?

Is it bioengineered?

You could be regulated under-

- **NIH Guidelines**
- **Toxic Substances Control Act (TSCA)**
- **Plant Protection Act**

US Coordinated Framework for the Regulation of Biotechnology

1986 – Present

Lead Regulatory Agencies:

- National Institute of Health (NIH) oversees research
- Environmental Protection Agency (EPA)
- Department of Agriculture (USDA)
- Department of Health and Human Services, Food and Drug Administration (FDA)

Coordinated Framework Oversight of Laboratory Research

National Institutes of Health (NIH) Guidelines (1976 – Present)

“recombinant DNA molecules”

- (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or
- (ii) molecules that result from the replication of those described in (i) above.

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

Coordinated Framework Oversight of Laboratory Research

National Institutes of Health (NIH) Guidelines (1976 – Present)

- Mandatory for recipients of federal funds
- Voluntary compliance by private sector
- Science-based/peer review/public meetings
 - Recombinant DNA Advisory Committee (RAC)
 - Institutional Review Boards (IRBs)

TSCA Regulation of Certain Microorganisms

- US Environmental Protection Agency (EPA) regulates new microbial products of biotechnology under the Toxic Substances Control Act (TSCA)
- TSCA can require obligations regarding reporting, management, storage, containment, use and disposal
- Here, reporting required for “new” microorganisms (62 FR 17910)
- Reporting requirements can be extensive and lead to further regulation

TSCA – What's Covered?

“microorganism”

- an organism
- classified using the 5-kingdom classification system of Whittacker,
- in the kingdoms monera (or Procaryotae), Protista, Fungi
- and the Chlorophyta and the Rhodophyta of the Plantae
- and a virus or virus-like particle
 - Specifically includes red and green algae

TSCA – What’s Covered?

“new”

- “new” means “intergeneric”
- a microorganism formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera.
 - Contains a mobile genetic element which was first identified in a microorganism in a genus different from the recipient microorganism
 - Does not include a microorganism which contains introduced genetic material consisting of only well-characterized, non-coding regulatory regions from another genus

TSCA Regulation of Certain Microorganisms

Reporting Will Require Data

- Transformation Systems
- Donor Genes
- Regulatory Sequences
- Genetic Analysis and Stability
- Existing Health and Safety Data

Bioengineered and Outside

Bioengineered algae being cultivated outside falls within USDA's statutory authority under the Plant Protection Act

- May trigger similar data requirements as TSCA
- USDA currently amending rules, has specifically referenced treatment of algae as it considers new rules
- Outdoor growing may trigger other federal environmental statutes

Plant Protection Act – What's Covered?

- Noxious Weed - any plant or plant product that can directly or indirectly injure or cause damage to agriculture, irrigation, navigation, natural resources, the public health, or the environment.

7 U.S.C. § 7702(10).

- PPA regulation can include regulation of release into the environment.

7 U.S.C. § 7702(9)(E).

Plant Protection Act – What's Covered?

- USDA can regulate any “article” if necessary to prevent dissemination of a plant pest or noxious weed

7 U.S.C. § 7712(a).

- “article” - any material or tangible object that could harbor plant pests or noxious weeds.

7 U.S.C. § 7702(1).

USDA Data Reviews

Potential Adverse Effects

- Weediness
- Increase weed potential of other plants
- Impacts on beneficial, threatened or endangered organisms
- Impacts on biodiversity

National Environmental Policy Act (NEPA)

Any federal action that could have a significant environmental impact requires environmental review

- Discuss likely impacts
- Identify reasonable alternatives
- Publicly available
- Not a risk assessment or decision document
- Can be triggered by federal funding or permitting

Endangered Species Act (ESA)

Any federal action that could have an impact on threatened or endangered species or critical habitat requires consultation with Fish and Wildlife Services or National Marine Fisheries Services

- Can be triggered by federal funding or permitting
- Private actions can sometimes trigger ESA

Where are you growing it?

NEPA and ESA can be triggered without use of biotechnology

- Federal funding
- Federal permitting

- US Army Corps of Engineers (USACE) Permit 404

Are you in the waters of the United States?

Discharge of Dredge or Fill Material Into Water (Section 404 Permit)

Permit required for any discharge of dredged or fill material into waters of the United States

“waters of the United States” – rivers, lakes, streams, tidal waters and most wetlands

Certain agricultural exceptions or general permits

You're feeding them what!? EPA Regulation

- National Pollutant Discharge Elimination System (NPDES) Permit – may be administered either by EPA or a state – required for discharges into an aquaculture project
- Are EPA regulations regarding underground injection controls triggered?

What does your state require?

California requires 17 different permits for aquaculture

- Check state Department of Agriculture
- Check state Department of Natural Resources
- Check state Fish and Game Commission
- Check state Water Quality Board
- Check restrictions on energy production
- Don't stop at state economic development board!

Local Regulation

- Are there local water controls/permits needed?
- Are there local waste discharge regulations that are triggered?
- Are there local land use/zoning restrictions?

Even if you're growing inside...

- You still may face some environmental regulatory requirements.
- NPDES permit required for waste discharge from indoor facilities
- May trigger state water use regulations

Maximize federal, state and local incentives

- Tax Relief for Environmental Remediation
- Carbon Credits
- State agricultural support – grants, etc.
- Partnership with other local industries

Talk to Your Regulators!

- State
- Federal
- Local

Talk to Your Regulators!

(and get it in writing!)