Under-appreciated Regulatory Barriers to Commercialization of Algae and Algal Products

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Algae Processing and Use

Uses regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA)

Also regulated under the Toxic Substances Control Act (TSCA)

Uses regulated under TSCA

- Food/Feed
- Cosmetic
- Fuel
- Industrial Intermediate
Uses TSCA Regulates

- TSCA is the “catch all” chemical statute; it regulates uses not regulated by other federal statutes
- TSCA does not regulate:
  - Food, food additives, food contact materials, animal feed, drugs, drug intermediates, medical devices, cosmetics, or personal care products
  - Tobacco and tobacco products
  - Pesticides
  - Nuclear source materials and radioactive byproducts
  - Munitions
  - Plant pests
TSCA Inventory

- **TSCA Inventory** -- A list of all chemical substances that may be manufactured or imported into the U.S. for TSCA purposes
  - May not reflect chemicals currently in commerce

- TSCA Inventory status determines whether a substance is “new” or “existing”
  - **Existing Chemical Substance** -- Any chemical substance listed on the TSCA Inventory
  - **New Chemical Substance** -- Any chemical substance *not* listed on the TSCA Inventory
TSCA Inventory (cont’d)

- All chemicals in commerce MUST be on the TSCA Inventory or be eligible for an exemption

  - Exemptions without reporting requirement:
    - No commercial purpose (e.g., impurities)
    - Research and development
    - Non-isolated intermediates
    - Most articles

  - Exemptions with reporting requirements:
    - Low volume, test market, low release/low exposure (all require notification)
    - Certain polymers
Naturally Occurring Substances

- Automatically included on Inventory
- Defined as: unprocessed or processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or extracted from the atmosphere by any means
- Examples are raw agricultural commodities, crude oil, rocks, ores, minerals
- Chemical modifications (e.g., acid/base treatment, redox reactions, distillation) nullify naturally occurring designation
- Definition is process-specific
  - Grinding, filtering, washing, drying generally fit the definition
  - Using water, but not steam, to extract a substance generally fits the definition
Microbes Regulated by TSCA

- Microbes used for TSCA purposes are regulated by TSCA
  - Not TSCA: Brewers yeast used to make liquor
  - TSCA: Brewers yeast used to make fuel ethanol
- Microbes are likely naturally occurring unless:
  - Genetic material from a different genus is introduced
- Microbes not listed on the Inventory require a Microbial Commercial Activity Notice (MCAN)
TSCA Nomenclature

- Based on Chemical Abstracts Service (CAS) identities
- Not all CAS identities are appropriate for TSCA
- There are two classes of TSCA identities
  - Class I substances:
    - Single, defined substances
    - *E.g.*, ethanol; 1,4-butandiol; anthracene
  - Class II substances:
    - Single formula, multiple structures
      - Xylenes (mixed isomers)
    - Definite molecular formulas, unknown structural diagrams
      - Aluminum cerium nickel sulfide, AlCe$_3$NiS$_7$
    - No definite molecular formula and either partial or no structural diagrams ("unknown or variable composition, complex reaction products, or biological materials" or UVCBs)
    - Identity may include source and process
TSCA Common Misconceptions

- “My material is naturally occurring, so I don’t have to file a PMN.”
- “My material is not toxic, so I’m not covered by the Toxic Substances Control Act.”
- “My material is GRAS, so I’m not covered by the Toxic Substances Control Act.”
- “I make my product using fermentation, so it’s naturally occurring.”
- “My material is the same as an existing chemical.”
Algal Products TSCA Overview

- Intergeneric algae are reportable
- Spent biomass byproduct may be reportable depending on use
- Mostly Class II/UVCB products
- Algae companies manufacturing UVCBs should be especially careful about substance identity
- Algae companies using byproducts or waste as a feedstock should engage with their supplier about the TSCA status of that feedstock
Food Additives

- Options for use as a food additive
  - Generally Recognized as Safe (GRAS)
  - Food additive petition (FAP)
- Scientific burden is the same: demonstrate safety for the intended use
- Specific to “intended conditions of use”
- GRAS data (and status) are public
- Process requires >5 years
Food Additives (cont’d)

- Food additives are generally less prescriptive from a source perspective

  ➢ 21 C.F.R. § 172.860 -- Fatty acids

  The food additive fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The food additive consists of one or any mixture of the following straight-chain monobasic carboxylic acids and their associated fatty acids manufactured from **fats and oils derived from edible sources**: Capric acid, caprylic acid, lauric acid, myristic acid, oleic acid, palmitic acid, and stearic acid
Cosmetics

- Entity that offers cosmetic to market (usually a formulator) is responsible to ensure safety
- Formulator typically expects ingredient manufacturer to document safety
- There is no list (or inventory) published by the U.S. Food and Drug Administration (FDA) of approved ingredients
- Cosmetic Ingredient Review expert panel (non-governmental organization) provides independent review of ingredients
Be Careful about Claims

- Do not make claims about medical effects (drugs)
  - Avoid: Stimulates cell renewal/regeneration; DNA repair/protection; skin repair/protection; easily absorbed; increases circulation
- Do not make claims about pesticidal or biocidal effects (pesticides or drugs)
  - Avoid: Kills/controls/prevents growth
Regulatory Takeaway

- Understand regulatory burdens
- Think strategically about:
  - Target markets/uses
  - Global markets
- Include regulatory timeline in business planning
- Seek assistance
  - In preparation, review, and communication with regulators
THANK YOU

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