TSCA Nomenclature and Chemical Identity Issues for Algae-Derived Products

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Uses TSCA Regulates

- The Toxic Substances Control Act (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
Algae Processing and Use

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

Algae  Refine

Also regulated under TSCA

Uses regulated under TSCA

Food/Feed

Cosmetic

Fuel

Industrial Intermediate
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)
    - Some 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-butanediol; anthracene
  - Class II substances:
    - Single formula, multiple structures
      - Xylenes (mixed isomers)
    - Definite molecular formulas, unknown structural diagrams
      - Aluminum cerium nickel sulfide, $\text{AlCe}_3\text{NiS}_7$
    - No definite molecular formula and either partial or no structural diagrams ("unknown or variable composition, complex reaction products, or biological materials" or UVCBs)
TSCA Nomenclature of UVCBs

- Identity may include source and process

Straight Run, Kerosene (petroleum)

A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C16 and boiling in the range of approximately 180° C to 300° C (356° F to 572° F)
TSCA Nomenclature of UVCBs (cont’d)

Corn oil

Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic, and stearic (Zea mays)

Soybean oil

Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic, and stearic (Soja hispida)
Source-Based Identities and the Supply Chain

- Soybean oil
- Fatty acids, soya
- Fatty acids, soya, ethoxylated

- Corn oil
- Fatty acids, corn-oil
- Fatty acids, corn-oil, ethoxylated

Not interchangeable identities
Feedstock Flexibility

- “Soap and Detergent Association (SDA) Nomenclature”
  - System to provide some flexibility on feedstocks
  - Categorizes surfactant supply chain substances into alkyl ranges and functional classes
  - Draws equivalence between natural sources and synthetic equivalents
### SDA Nomenclature Sources

<table>
<thead>
<tr>
<th>Vegetable</th>
<th>Animal</th>
<th>Marine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avocado</td>
<td>Peanut</td>
<td>Herring</td>
</tr>
<tr>
<td>Babassu</td>
<td>Rapeseed</td>
<td>Menhaden</td>
</tr>
<tr>
<td>Castor</td>
<td>Rice Bran</td>
<td>Salmon</td>
</tr>
<tr>
<td>Coconut</td>
<td>Safflower</td>
<td>Sardine</td>
</tr>
<tr>
<td>Corn</td>
<td>Safflower</td>
<td>Sperm Body</td>
</tr>
<tr>
<td>Cottonseed</td>
<td>(high oleic)</td>
<td>(whale)</td>
</tr>
<tr>
<td>Crambe</td>
<td>Sesame</td>
<td>Sperm Head</td>
</tr>
<tr>
<td>Linseed</td>
<td>Sorghum</td>
<td>(whale)</td>
</tr>
<tr>
<td>Olive</td>
<td>Soybean</td>
<td>Whale</td>
</tr>
<tr>
<td>Oiticica</td>
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<td></td>
</tr>
<tr>
<td>Palm</td>
<td>Tung</td>
<td></td>
</tr>
<tr>
<td>Palm-kernel</td>
<td>Wheat Germ</td>
<td></td>
</tr>
</tbody>
</table>

- Oils with fatty acids that may be called $\text{C}_{16}\text{-C}_{18}$ and $\text{C}_{18}$ unsatd.

- “Alkyl groups derived from other natural sources are not covered by this procedure”
SDA Identities and the Supply Chain

- Glycerides, $\text{C}_{16}-\text{C}_{18}$ and $\text{C}_{18}$-unsatd.
- Fatty acids, $\text{C}_{16}-\text{C}_{18}$ and $\text{C}_{18}$-unsatd.
- Fatty acids, $\text{C}_{16}-\text{C}_{18}$ and $\text{C}_{18}$-unsatd., ethoxylated
SDA Identities and the Supply Chain (cont’d)
Sources Not Eligible for SDA Nomenclature

- Tall oil
- Jatropha oil
- Camelina oil
- Waste oils and grease
- Algal oils
Algal Products TSCA Overview

- Intergeneric algae are reportable
- Spent biomass byproduct may be reportable depending on use
- Mostly class 2/UVCB products
- Algae companies manufacturing UVCBs should be especially careful about substance identity
- Companies using byproducts or waste as a feedstock should engage with their supplier about the TSCA status of that feedstock
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.”
Always Check the TSCA Status

- Is it excluded from TSCA?
- Is it exempted from TSCA?
- If not, verify identity, then check Inventory status

TSCA Inventory is available for download on EPA’s website: www.epa.gov

Inventory status also available via EPA’s online Substance Registry Services

- If not on public Inventory, determine if listed on the confidential Inventory
  - Via Bona Fide Intent to Manufacture or Import Notice
Section 5 -- New Chemicals Notification

- Substances not listed on the TSCA Inventory require a Premanufacture Notification (PMN)

- PMN must include:
  - Identity, structure, anticipated uses, anticipated production volume, any test data that you already have, expected releases and exposures from processing and use

- If manufactured (not just imported), must also include:
  - Starting materials, manufacturing process, expected releases and exposures

- May include optional Pollution Prevention (P2) Statement
P2 Statement

- A P2 Statement is the submitter’s opportunity to tell EPA reviewers about the P2 benefits of the substance.
- All green chemistry-related PMNs should have one.
- P2 benefits may be for feedstocks, process, or substance itself.
- EPA may use P2 information to make a relative risk determination and allow the substance to proceed without regulation (or with reduced regulatory burden).
- Submitter may receive Pollution Prevention Recognition, which is public recognition of the P2 benefits of the technology.
Summary

- TSCA is the catch-all chemical regulation
- Despite its name, TSCA applies to all chemicals used for TSCA purposes, whether toxic or not
- “Naturally occurring” is narrowly defined
- Nomenclature of UVCBs is complex
  - Source and process may affect identity
  - SDA Nomenclature closed to novel sources
- Byproduct exemption is complex
- Chemicals not listed on the Inventory (and not exempt) require notification
  - Submit pollution prevention information
- Substances on the Inventory are subject to on-going reporting requirements under Chemical Data Reporting (CDR) rule
THANK YOU

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