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Legal and Regulatory Considerations for Renewable Chemical Production

Nebraska Ethanol Board
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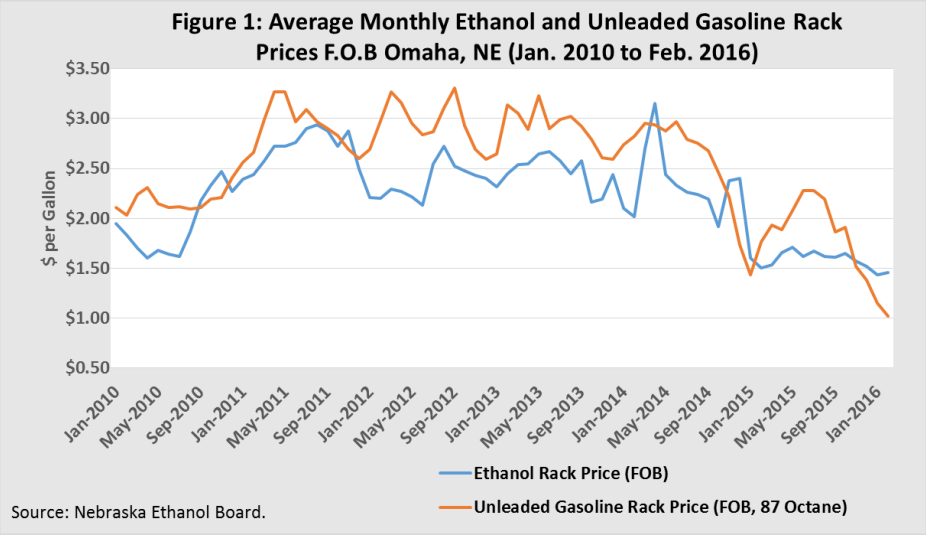
Overview

- Challenges in Ethanol Market
- Opportunities in Chemicals Markets
- Introduction to Toxic Substances Control Act (TSCA)
- Other Regulatory Options
- Plan Ahead

Challenges in the Ethanol Market

- Renewable Fuel Standard is unpredictable
  - Will it continue?
  - What will the blend rate be?
- Drop in total fuel consumption
- Fermentation overcapacity



Chemical Production Value Proposition

- Ethanol <$0.20/pound
- Chemical intermediates $0.50-$5/pound
- Specialty chemicals >$10/pound

Chemical Products

- We use “chemical products” in a broad sense -- as differentiated from articles
- Articles are manufactured to have a specific physical design to perform a function
  - A copper ingot is a chemical
  - A copper wire is an article
- “Particles are never articles”
- Need to recognize how regulatory oversight may change depending on the chemical product

Statutory Oversight of Chemical Substances

- Chemical control falls under a number of U.S. statutes and a number of federal agencies
- Federal Food, Drug, and Cosmetic Act (FFDCA) -- Food and Drug Administration (FDA)
  - Food/food additives, feed, food contact materials
  - Drugs/pharmaceuticals
  - Medical devices
  - Tobacco products
  - Cosmetics

Statutory Oversight of Chemical Substances

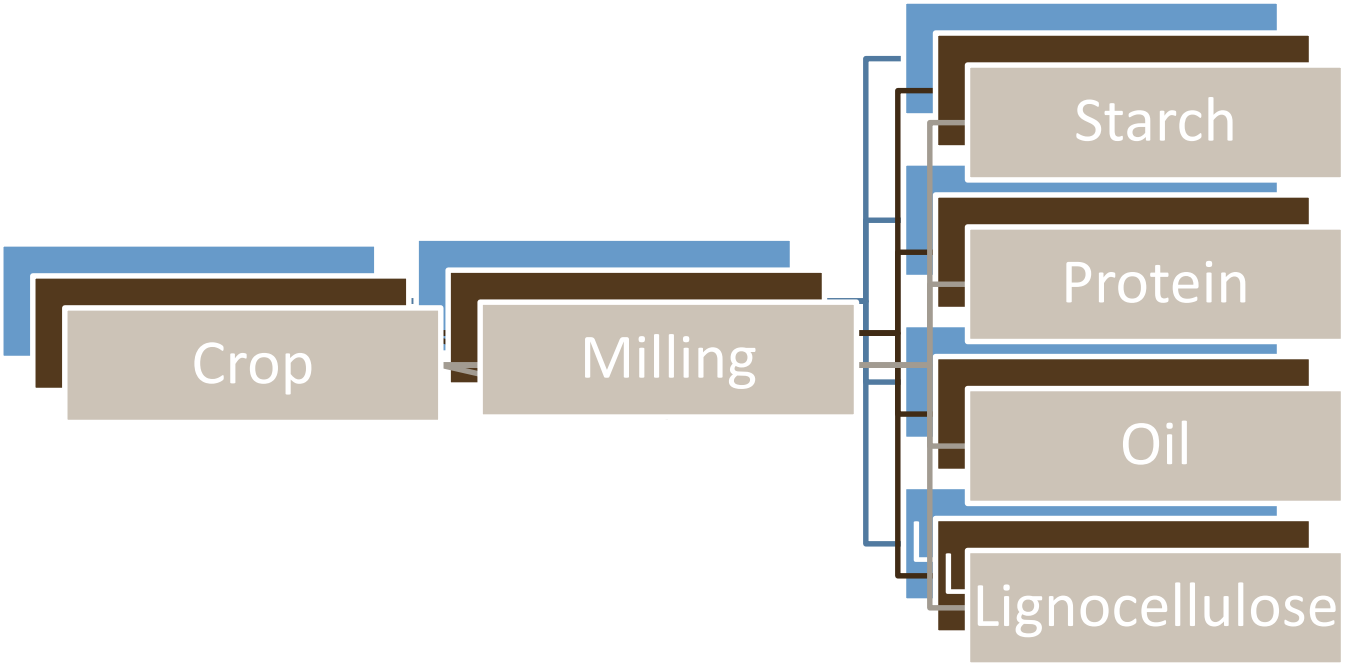
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) -- U.S. Environmental Protection Agency (EPA)
  - Pesticide active and inactive ingredients
  - Pesticide formulations
- TSCA -- EPA
  - Catch-all
  - Chemical substance is defined by what is not regulated by other authorities: not a food, drug, cosmetic, pesticide
- Ethanol also falls under Alcohol, Tobacco, and Firearms (ATF)
- One substance may be used across many applications and be subject to each of the separate statutes and related regulations

Feedstocks, Intermediates, Byproducts, and Coproducts

- Feedstocks, intermediates, byproducts, and coproducts are also chemical substances
  - Each is also subject to regulatory oversight
- Need to strategize and account for the entire value chain

Statutory View of Value Chain

- Food/feed products/FDA
- Cosmetic ingredients/FDA
- Chemicals/EPA



Actual value chain may be much more complex

Why Separate Consideration for Chemical Products?

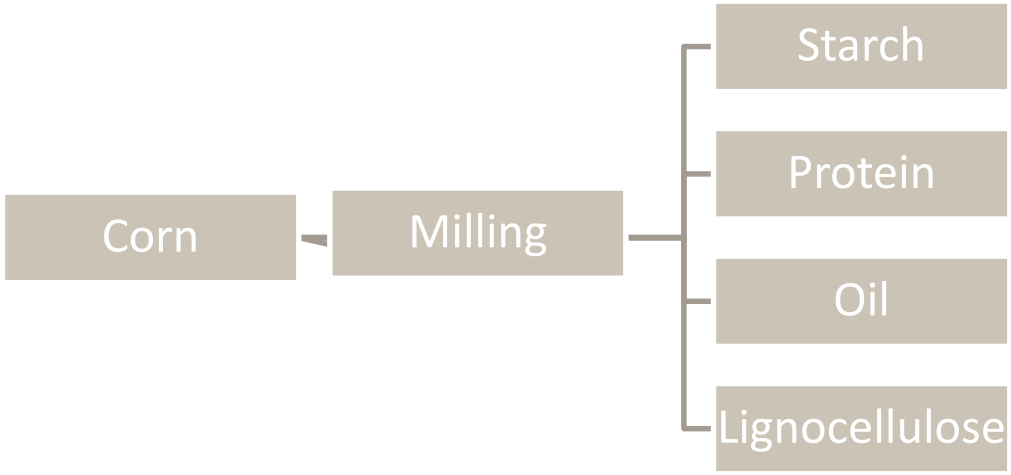
- History of statutes
  - 1910 -- FIFRA
  - 1938 -- FFDCA
  - 1976 -- TSCA
- Specific concerns lead to legislation

Quick Introduction to TSCA

- Prior to manufacture or import, a substance must be:
  - Listed on the TSCA Inventory (an “existing chemical”)
  - Be subject to a premanufacture notice (PMN) (a “new chemical”) or
  - Be eligible for an exemption

TSCA View of Corn Milling

- Starch (CAS RN 9005-25-8)
- Glutens, corn (CAS RN 66071-96-3)
- Corn oil (CAS RN 8001-30-7)
- Lignocellulose (CAS RN 11132-73-3)



- Are these substances naturally occurring?

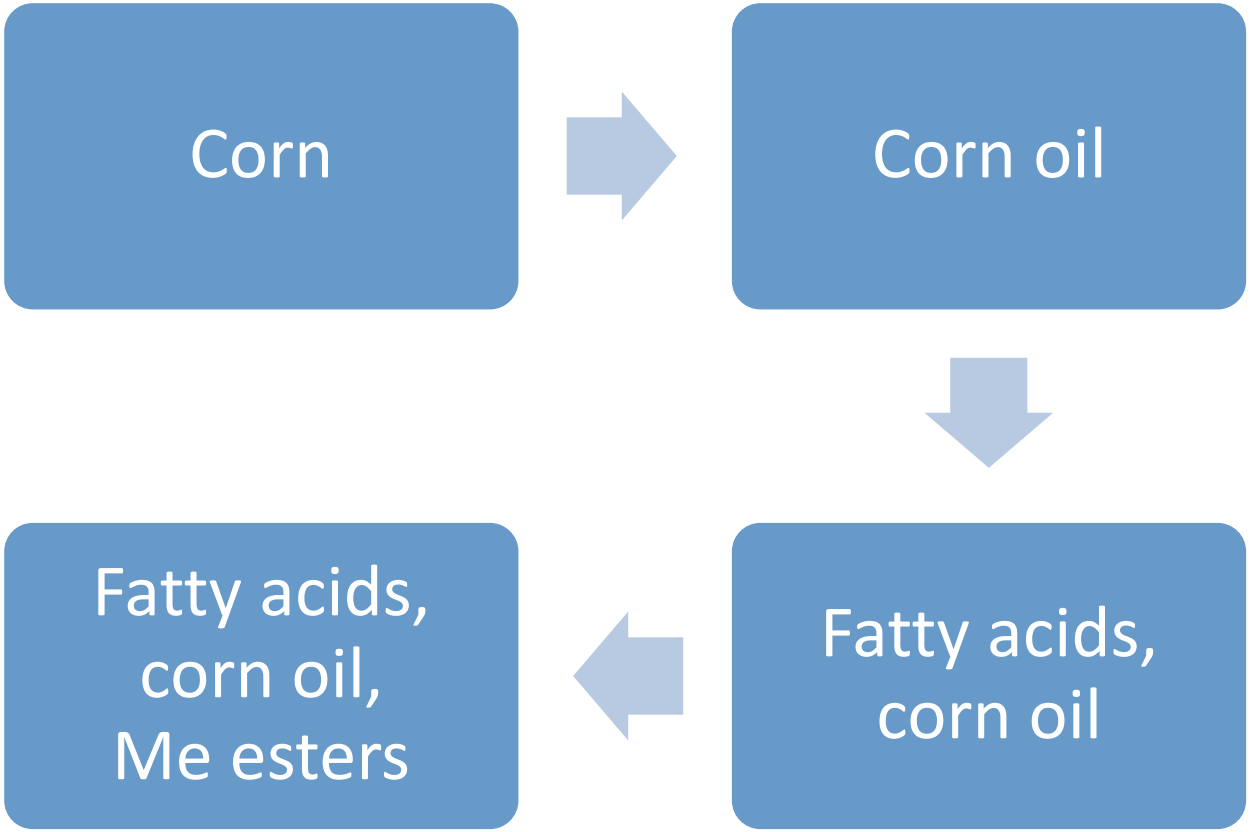
TSCA Definition of Naturally Occurring

- Naturally occurring substances are automatically included on the TSCA Inventory (may also be explicitly listed)
- Any chemical substance which is naturally occurring and which is:
  - Unprocessed, processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or which is extracted from air by any means
- Examples include: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals
- Any other chemical treatment voids the naturally occurring designation
- Steeping process in wet milling involves chemical treatment (sulfur dioxide, lactic acid)

What about GRAS (Generally Recognized as Safe)?

- GRAS is an FDA designation
- Safe for its intended use
- Confers no status to non-food uses

Example of Corn Supply Chain

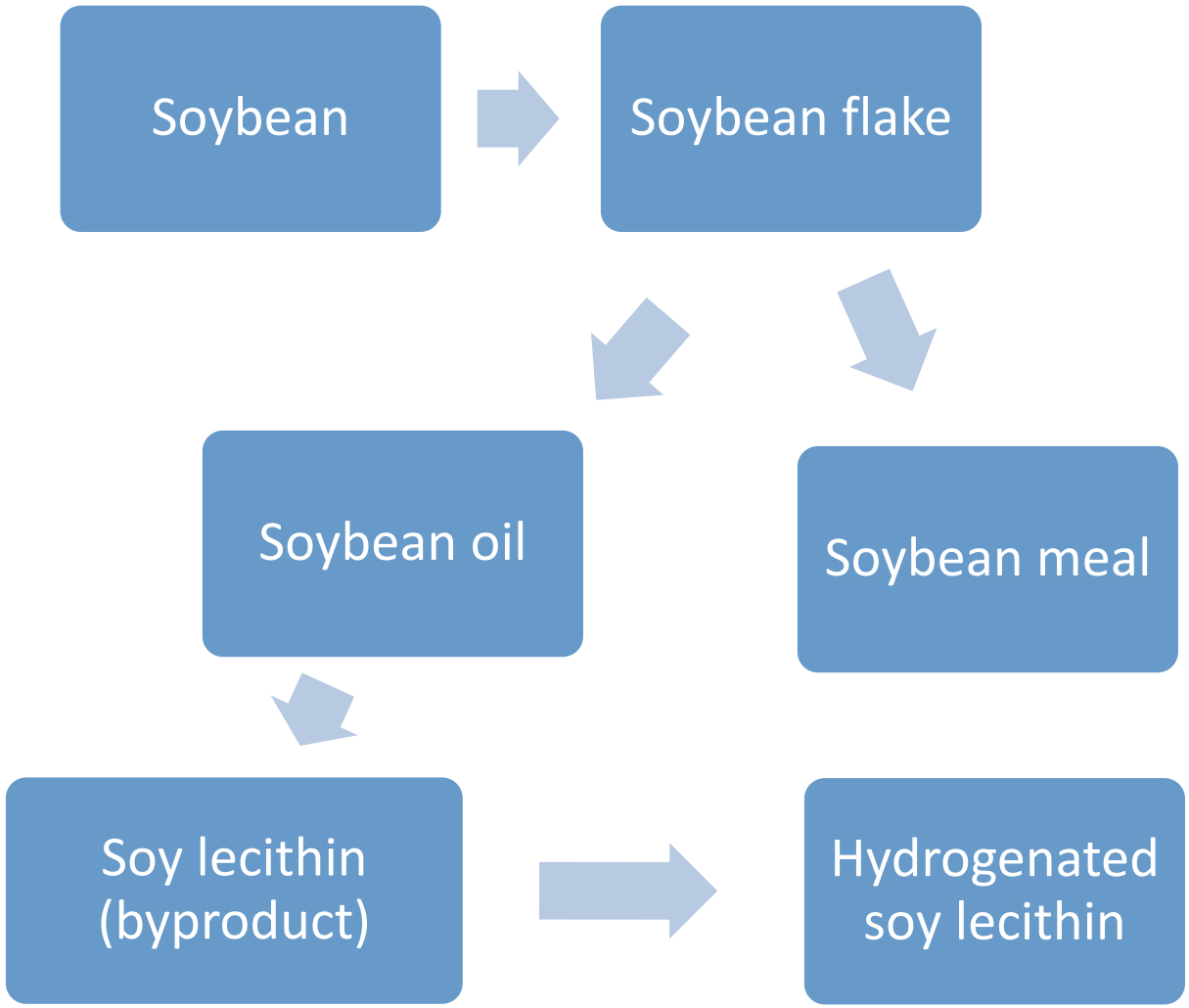


All substances listed on TSCA Inventory

What about Byproducts?

- Byproducts must also be listed unless:
  - Disposed of as waste
  - Used for soil enrichment
  - Burned as a fuel
  - Used to extract a chemical component that is already present
- Impurities are exempt (only if unintentionally present)

Soybean Milling



Ethanol

- Ethanol is used across statutory authorities
  - Food
  - Cosmetic ingredient
  - Drug
  - Anti-microbial
  - Industrial solvent
  - Chemical intermediate
  - Fuel

TSCA View of Ethanol Production

- Sugar source must be listed (starch or hydrolyzed starch syrups)
- Microbe must be listed (brewers yeast, modified yeast, intergeneric yeast)
- Ethanol (listed)
- Distillers grains (byproduct, not listed) may be used animal feed (food and feed are excluded from TSCA)

TSCA View of Chemical Production by Fermentation

- Sugar source must be listed
- Microbe must be listed (intergeneric microbe)
- Chemical product must be listed (*e.g.*, 1,4-butanediol, 1,3-propanediol)
- Distillers grains (byproduct, not listed)
  - Need to be careful about use -- FDA approval prior to using as feed

TSCA View of Chemical Identity

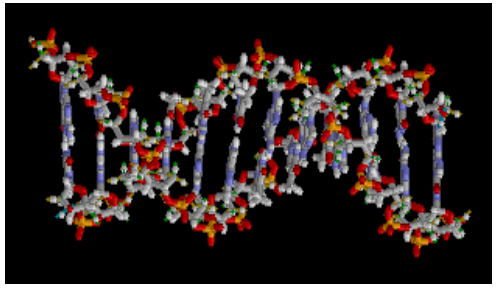
- Class 1 -- single defined structure
  - Ethanol
  - 1,3-propanediol
- Class 2 -- UVCB (unknown, variable, complex, or biological substance)
  - UVCBs -- cannot assume that a novel product is “the same as” an existing one
- New chemicals require PMN

UVCB Substances

- Often includes source
  - Fatty acids, corn oil
  - Fatty acids, soya
- May include process
  - Starch, hydrolyzed
  - Starch, acid-hydrolyzed
  - Starch, base-hydrolyzed
- May include both
  - Hydrogenated soy lecithin

TSCA View of Microbe Identity

- Microbes are considered chemical substances
- Naturally occurring microbes are automatically listed on TSCA Inventory
- Intergeneric microbes are not naturally occurring
  - Requires Microbial Commercial Activity Notice (MCAN)



Who Has the TSCA Obligations for PMN or MCAN?

- Manufacturer or importer of the substance or microbe
- Often technology developer will list the chemical and/or microbe
  - Licensee can rely upon listing

Other TSCA Obligations

- Quadrennial Chemical Data Reporting (CDR)
  - Substances manufactured or imported
- Substantial risk notices

Helpful TSCA Exemptions

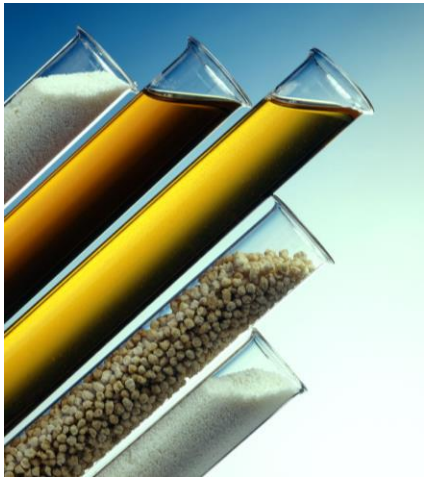
- Polymer exemption
- Research and Development (R&D) exemption
- Export only exemption

Other Options -- Cosmetic Ingredients

- Includes makeup, personal care products (shampoo, body wash)
- In U.S., regulatory obligation falls on finished cosmetic manufacturer
  - Finished cosmetic manufacturer usually requires supplier to demonstrate safety

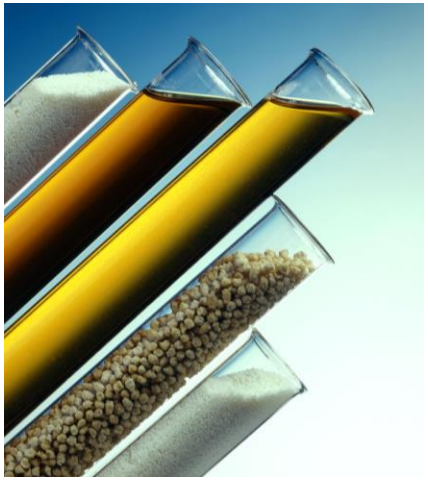
Other Options -- GRAS Food Ingredients

- May be able to demonstrate safety without extensive testing
- Depends on robust body of science
- Requires review by panel of experts



Other Options -- Food Additive Petition

- Center for Food Safety and Applied Nutrition
- Extensive testing likely required
- Demonstrate safety



Other Options -- Animal Feed

- Center for Veterinary Medicine
- Higher safety burden for livestock feed

Market Strategy

- Do not neglect regulatory considerations in your business plans
- Understand the timeframes and burdens for a product for various uses
- Notification/registration, testing
- Consider global opportunities

Plan Ahead

- PMN, MCAN -- 6-18 months
- Cosmetic ingredient -- 6-18 months for testing
- China; Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) registration -- depends on tonnage, 1-3 years with testing
- U.S. food additive petition -- 2-5 years
- U.S. feed additive -- 2-5 years
- U.S. pesticide registration -- 1-5 years
- Integrate U.S. and global testing, registration, and commercialization plans

Engage Early and Get Help

- Engage with supply chain
  - Develop agreement about meeting regulatory obligations
- Engage with experts
  - Get help building a road map for testing, notification, and registration
- Engage with regulators
  - Management level to give an overview
  - Staff level to discuss scientific details

Summary

- Ethanol presents challenges
- Changing to other chemicals are an opportunity
- Must account for regulatory obligations if changing product
- Build a road map
- Engage with stakeholders
  - R&D, business, EH&S
  - Consultants
  - Supply chain agreements
  - Regulators

THANK YOU

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