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Manufacturing Alcohol to Combat a Public Health Emergency:

Insights on Regulatory and
Quality Requirements





Ethanol for Food, Pharma and Fuel Applications

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Just a bit about me...



- 1994: Started at largest distillery in the world. ~70 different ethanol products.
- 2000: Transferred to largest corn processing plant in the world. Became a food ingredient expert.
- 2007: Worked for ethanol trade association.
- 2015: Started ethanol consulting.
- 2018- Present: Building domestic and global ethanol markets.

Ethanol Characteristics

- Water-white solvent that is flammable and consumable.
- Very water soluble, broad range of solubilities.
- Readily evaporates.
- Natural, biodegradable.
- Adds no odor or color.
- Can be used as a carrier.
- Agricultural derived, no fossil fuel.
- All types of ethanol can be produced at a single facility.

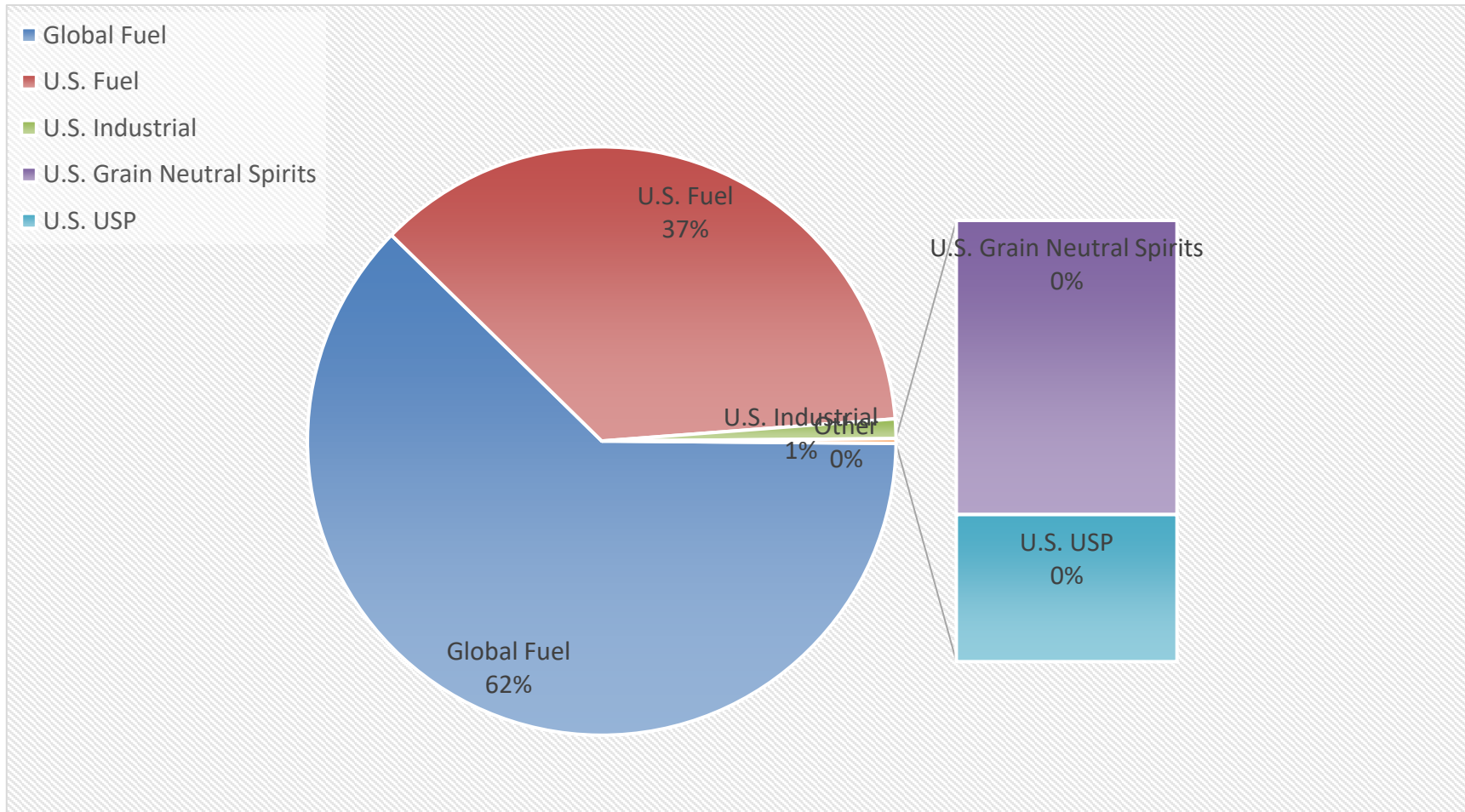
TYPICAL INDUSTRIAL ALCOHOL APPLICATIONS

Acetic acid • Adhesives and binders • Animal feed supplements • Antibiotics • Antifreeze • Antiseptic solutions • Bath preparations • Bay rum • Brake fluids • Candy glazes • Chemicals • Cleaning solutions • Coatings • Colognes • Cutting oils • Dentifrices • Deodorants • Detergents • Detonators • Disinfectants • Drugs and medicinal chemicals • Duplicating fluids • Dyes • External pharmaceuticals • Fluids • Food products • Fungicides • Hair and scalp preparations • Incense • Inks • Insecticides • Iodine solutions • Laboratory reagents • Lacquer thinners • Liniments • Lotions and skin creams • Mouthwashes • Perfumes • Petroleum products • Photoengraving dyes and solutions • Photographic chemicals • Photographic film and emulsion • Plastics • Polishes • Preserving solutions • Refrigeration • Rotogravure dyes and solutions • Rubber • Rubbing alcohol compounds • Scientific instruments • Shampoo • Shellac • Soaps • Soldering flux • Solvents and thinners • Stains • Sterilizing solutions • Theater sprays • Transparent sheetings • Vaccines • Vinegar • Vitamins • Witch hazel • Wood stains

These are just some of the hundreds of products made with industrial ethyl alcohol.



Sizing up the Ethanol Markets

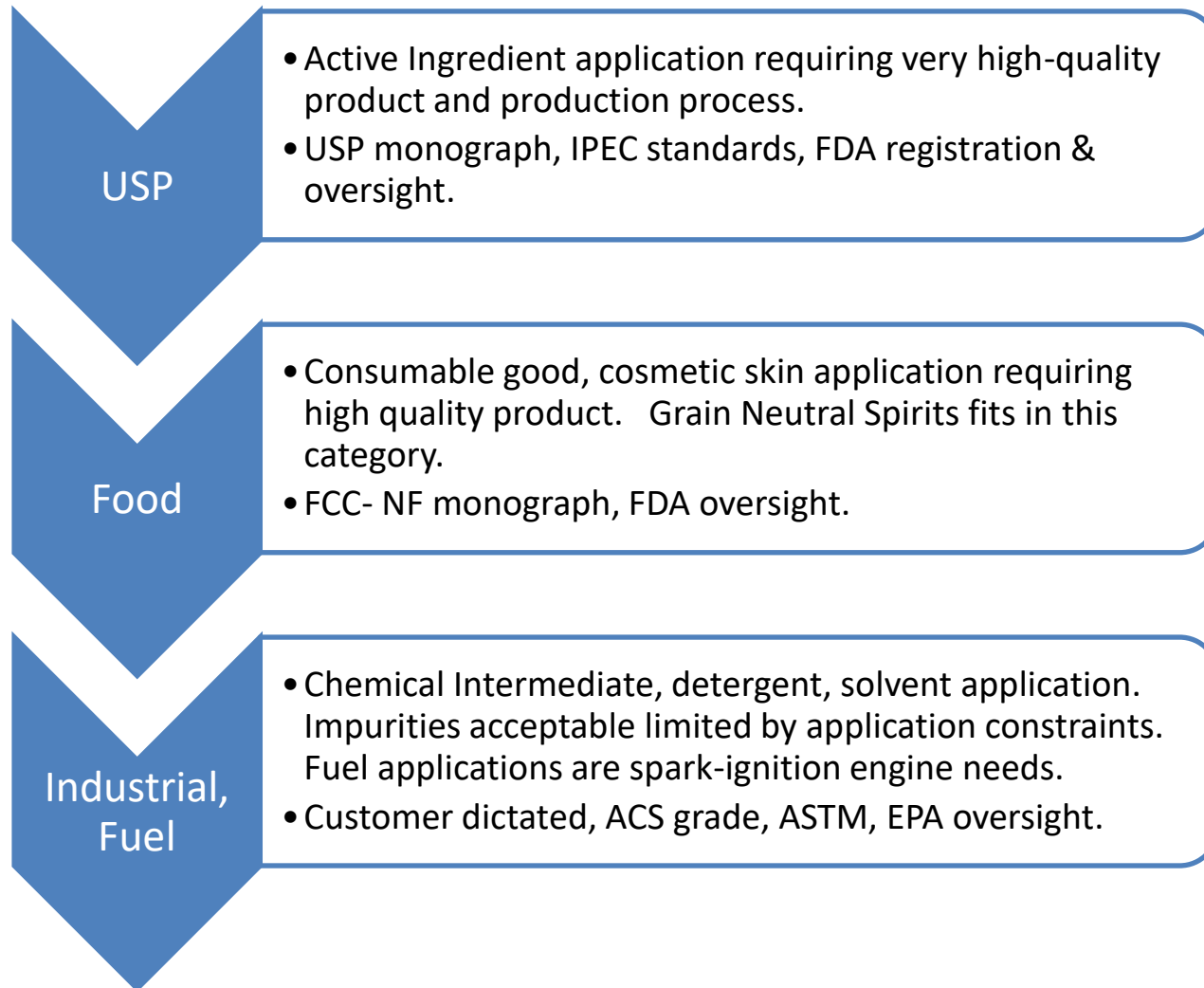


Ethanol by Application

- The fuel business is heavily regulated by Federal, state and local officials.
- There are rigorous customer expectations by the global oil companies.
- The non-fuel business is also heavily regulated.

Application	Grade, Regulatory Oversight	Example
Pharmaceutical	US Pharmacopeia (USP), IPEC, FDA, TTB	Hand Sanitizer, Drug formulation, Mouthwash
Food	Food Chemical Codex (FCC), FDA, TTB	Liquor/ Spirits, Vinegar, Flavorings
Cosmetics, Toiletries	Food Chemical Codex (FCC), FDA, TTB	Hair Spray, Lotions, Soaps
Detergents, Biocides	American Chemical Society (ACS), FDA, TTB	Contact cleaners, surface cleaners
Industrial Solvents	Customer dictated, TTB	Printing Inks, Mineral Spirits, Paint Thinner
Chemical Intermediates	Customer dictated, TTB	Polymers, plastics, glycol ethers (antifreeze)
Fuel	ASTM, EPA, TTB	Gasoline blending, Ethanol Flex Fuels

Purity & Regulatory Oversight Comparison



Ethanol has a standard slate of characteristics; impurities and limits are set by application needs:

Ethanol: Vol. %

Water: Vol. %

Methanol: Vol. %

Other impurities: ppm or not limited.

Nonvolatile matter:

Acidity: mg/l as acetic acid

Color: PtCo or other scale.

Permanganate Time: Minutes.

Ethanol Quality: Managing Multiple Standards

- USP Monograph Alcohol.
- FCC Monograph Alcohol
- ASTM D4806 Specification for Denatured Ethanol.



Designation: D4806 – 20

Standard Specification for Denatured Fuel Ethanol for Blending with Gasolines for Use as Automotive Spark-Ignition Engine Fuel¹



TABLE 1 Performance Requirements

Property	Limit	Method
Ethanol, % by volume, min	92.1	D5501
Methanol, % by volume, max	0.5	D5501
Solvent-washed gum content, mg/100 mL, max	5	D381
Water, % by volume (% by mass), max	1.0 (1.26)	D7923, E203, or E1064
Inorganic Chloride, mg/kg (mg/L), max	6.7 (5)	D7319 or D7328
Copper, mg/kg, max	0.1	D1688
Acidity (as acetic acid CH ₃ COOH) mg/kg, (% by mass) [mg/L], max	70 (0.0070) [56] (Note 2)	D7795
pHe	6.5 to 9.0	D6423
Sulfur, mg/kg, max	30.	D2622, D3120, D5453, or D7039
Existent sulfate, mg/kg, max	4	D7318, D7319, or D7328

Ethanol Industry Needs: Updates

Parameter	Current Entry	Proposed Change	Justification
Ethanol Content, Volume %	94.9% - 96.0%	94.9% to 96.5%	Natural azeotrope for ethanol distilling is 96.5%. De-proofing should not be a requirement.
Temperature, °C	15.56°C	Recognize 20°C	Recognition of both 15.56°C and 20°C.
Organic Impurities	GC method	Carrier gas (H ₂), Internal Standards,	Internal standard alongside recognition of GC technology will advance the use and efficiency of this important analysis.
Acidity	Phenolphthalein	Auto-titrator, Elimination of CO ₂ .	The current method is subjective and prone to false high due to CO ₂ interference.

Final Thoughts


- The USP monograph has not materially changed since its inception.
 - One exception: FDA prompted a change in Fall 2020.
 - Industry was not involved with this change.
- The industry has up to date laboratory analytical equipment that can be utilized.
 - There is also a great desire to improve the USP analytical techniques.
Example: Acidity, Gas Chromatography.
- We need to build relationships and education between government, USP and industry in order for ethanol to continue to grow and play a vital role in combatting this pandemic.



Thank you!

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Questions VIA the Q&A Feature:

- ▶ **Step 1:** Click on the Q&A icon  at the bottom of the screen. The Q&A panel will appear along the right-hand side of the WebEx screen



- ▶ **Step 2:** All questions/comments should be sent to [**All Panelists**]. By default, when sending a message, it will go to everyone. To send your question to [**All Panelists**], click on the drop-down labeled **To:** and select [**All Panelist**].
- ▶ **Step 3:** We ask that you include your **name** and the **organization** you are representing when submitting your question.
- ▶ The **Q&A monitor** for the event will ask your question to the speaker. Any unanswered questions will be answered by email.

Open Floor – Q&A with the Panel



Facilitators:
Danita Broyles & Andy Powers

Panelists:

- Stephen Andruski | USP
- Conner Curran | Dexterous DMCC
- Francis Godwin | U.S. FDA
- Robert Lafaver | USP
- Theresa Michelle | U.S. FDA
- Kristin Moore | KMoore Consulting LLC
- Andy Powers | Newton Enterprises
- Robert Shimahara | USP

Thank You



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