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# Manufacturing Alcohol to Combat a Public Health Emergency:

## Insights on Regulatory and Quality Requirements

# The Food Chemical Codex Ethyl Alcohol Monograph

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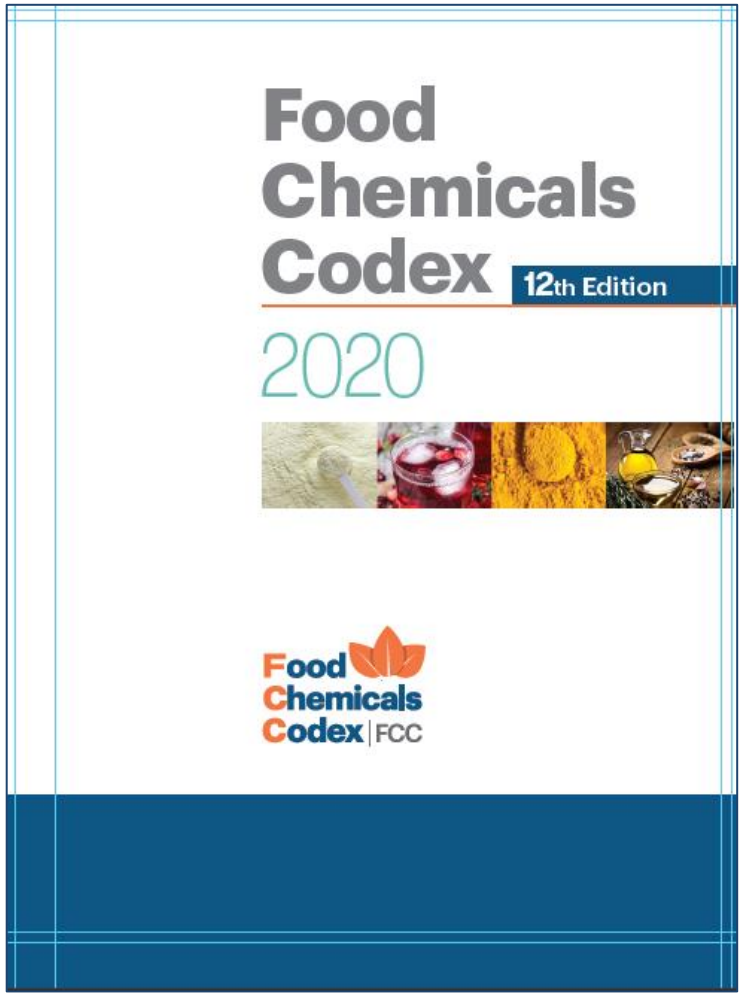
Food Chemicals Codex | FCC

# Brief Introduction to the FCC

# The Food Chemicals Codex

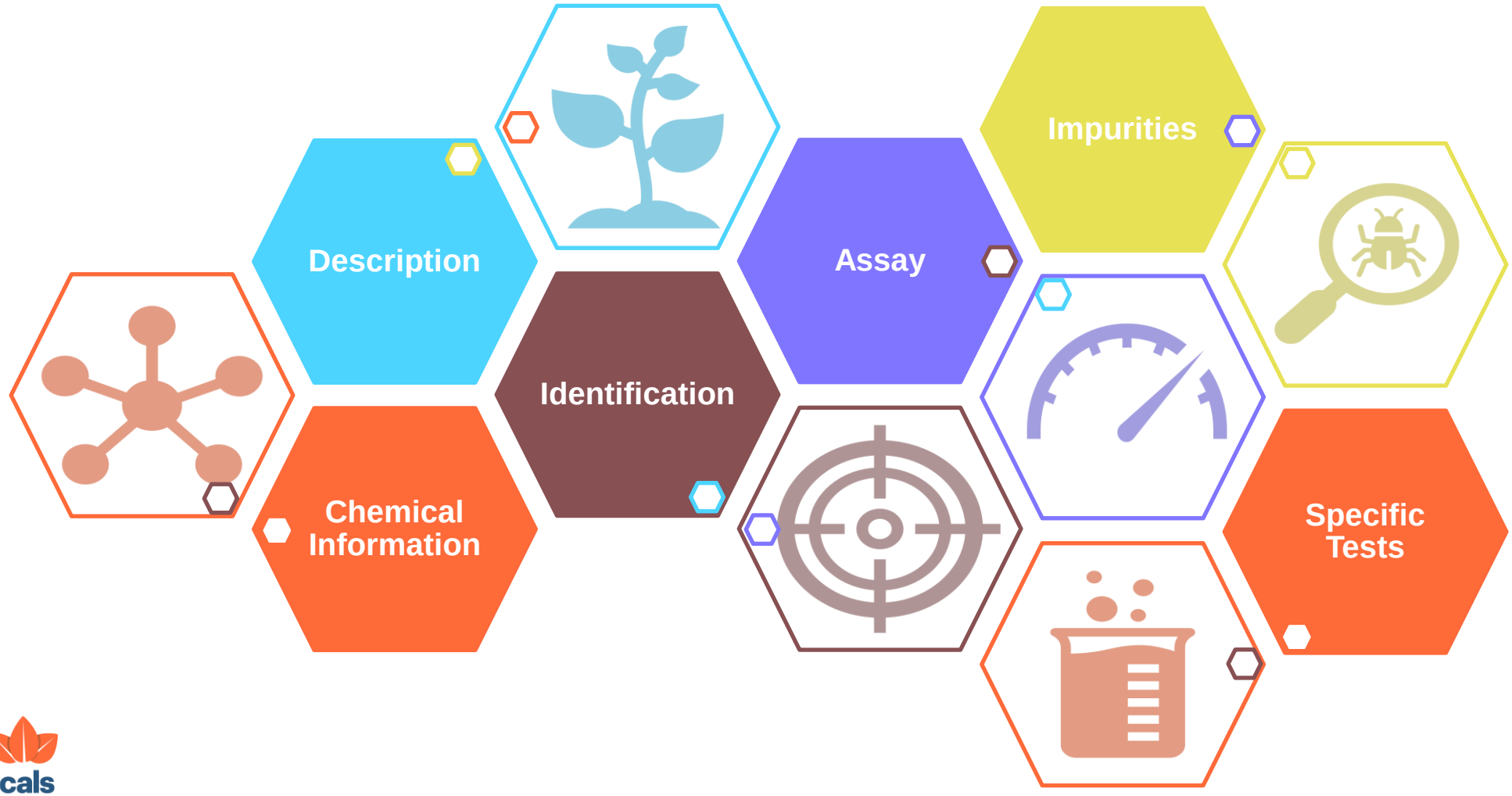
- The FCC was created by the US-FDA and the US National Institute of Medicine
  - To be “a compendium of standards designed especially for food chemicals”
- First edition published in 1968
- Currently published by USP
- >1250 standards for food additives, food ingredients, and other food chemicals



# FCC Contents

- More than 1250 monographs
  - Probiotics & prebiotics
  - Preservatives
  - Fats and oils
  - Infant formula ingredients
  - Dietary fibers
  - Gelling agents
  - Emulsifiers
  - Flavors
  - Sweeteners
  - Nutrients
  - Colorants
  - Filtration aids
  - Glazes
  - & More
- Guidance, including
  - More than 150 tests and assays
  - Food Fraud Mitigation Guide
  - Guidance on Developing and Validating Non-Targeted Testing

# Structure of an FCC monograph



# Hand Sanitizers and the FCC

# Extracts from FDA Guidance on Hand Sanitizers

- **Alcohol (ethanol) that is produced using fermentation and distillation processes typically used for consumable goods, and that is made in a facility used for producing consumable goods, may be considered for use in hand sanitizer, provided the alcohol meets the interim impurity levels in Attachment 1**

- **Alcohol derived from synthetic processes may be considered for use in hand sanitizer only if it meets USP or FCC grade.**

- **Alcohol produced in facilities normally producing fuel or technical grade alcohol (ethanol) may be considered for use in hand sanitizer provided the following circumstances are present:**
  - **(ii) the alcohol meets USP or FCC grade requirements or the conditions in Attachment 1**

- **FCC grade alcohol should be tested for impurities using the methods recommended in USP and confirmed to meet the limits in Attachment 1**

# Attachment 1

Table 1

| Impurity | Interim Limit under this policy |
|---|---|
| Methanol | NMT 630 ppm |
| Benzene | NMT 2 ppm |
| Acetaldehyde | NMT 50 ppm* |
| Acetal (1,1-diethoxyethane) | NMT 50 ppm |
| Sum of all other impurities | NMT 300 ppm |

We recommend using test methods described in USP.

# FDA Request to USP

- **July 30 Letter**

- **For the Alcohol and Dehydrated Alcohol monographs, we recommend moving the entire test for the Limit of Methanol from the Organic Impurities section to Identification - Test C. We recommend that USP consider appropriate approaches to introduce this test [to] any related USP-NF and FCC monographs as well.**

# FCC Ethyl Alcohol Monograph

# FCC Ethyl Alcohol Monograph

- First published in FCC First Edition, no updates since then
- Functions identified: extraction solvent or carrier
- Did not have an Identification Test
- Impurities Test for Methanol – Qualitative (at best)
  - Acceptance criteria – no violet color after procedure, LOD not specified
  - Information from stakeholders suggested that there was a problem with LOD

# FCC Ethyl Alcohol Monograph

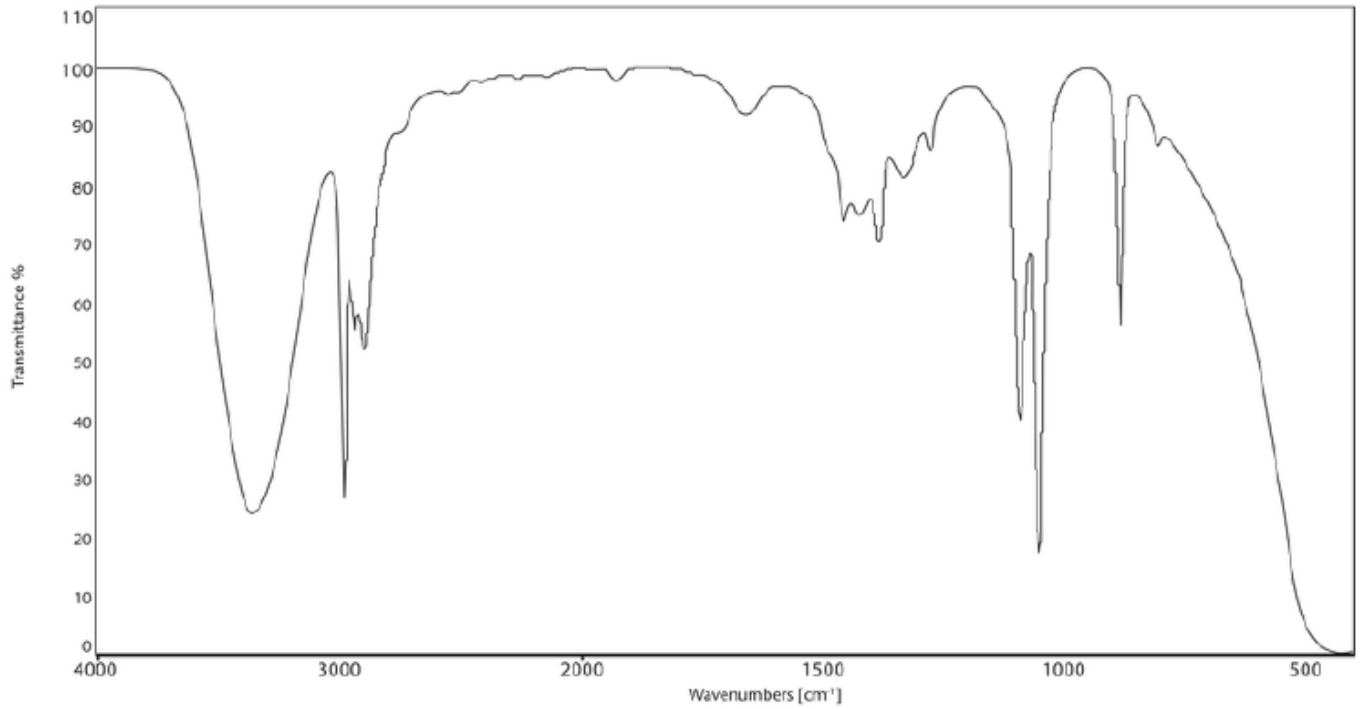
- To meet the FDA request and to protect public health, the Food Ingredients Expert Committee updated the Ethyl Alcohol Monograph
  - Added Identity test
  - Modernized methanol impurity test

# FCC Immediate Standard

- **Added Identification test – IR Spectrum**
  - **Corresponds to the international standard from the Joint Expert Committee on Food Additives**

• INFRARED SPECTRA, *SPECTROPHOTOMETRIC IDENTIFICATION TESTS, APPENDIX IIIC*

**Acceptance criteria:** The spectrum of the sample exhibits relative maxima at the same wavelengths as those of the spectrum below.



# Modernized Methanol Impurity Test

- **Added the USP-NF GC method**

▲• **METHANOL AND OTHER VOLATILE IMPURITIES**

**Sample solution A:** Ethyl Alcohol (substance under test)

**Sample solution B:** 300 µL/L of 4-methylpentan-2-ol in *Sample solution A*

**Standard solution:** 200 µL/L of methanol in *Sample solution A*

**System suitability solution:** 10 µL/L of methanol and 10 µL/L of acetaldehyde in *Sample solution A*

**Chromatographic system, *Appendix IIA***

**Mode:** GC

**Detector:** Flame ionization

**Column:** 0.32-mm × 30-m fused-silica capillary; bonded with a 1.8-µm layer of a 6% cyanopropylphenyl–94% dimethylpolysiloxane stationary phase

# Modernized Methanol Impurity Test

- **Same methanol acceptance criterion as in the USP-NF**

| Name | Acceptance Criteria |
|---|---|
| Methanol | NMT 0.5, corresponding to NMT 200 µL/L |
| Any other single impurity | NMT 1000 µL/L (calculated as 4-methylpentan-2-ol) |
| Sum of all impurities[a] | NMT 5000 µL/L |

# FCC Ethyl Alcohol Monograph Plans

- Assess methods and limits for additional impurities, considering
  - Regulatory limits for beverage alcohol
  - International harmonization
- Update monograph through normal process based on this information

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# THANK YOU

**For further information please contact FCC@usp.org**