FCC Monographs and Identity Standards
What are they and how are they created?

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Today’s Discussion

- Overview of FCC – Sections
- Monographs in FCC – Structure & Development
- Identity Standards in FCC – Structure & Development
- The FCC Forum Process
- Questions?
**Food Chemicals Codex (FCC)**

- Internationally recognized standards (including testing methods, specifications, and supporting reference materials) for food ingredients…

- Used as a benchmark for “food-grade”
### FCC Scope Over Time

<table>
<thead>
<tr>
<th>Category</th>
<th>Monographs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1966</strong></td>
<td>512 monographs</td>
</tr>
<tr>
<td><strong>2010</strong></td>
<td>~1100 monographs</td>
</tr>
<tr>
<td><strong>2018</strong></td>
<td>(over 1250 monographs)</td>
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</tbody>
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#### Food-grade chemicals
- Emulsifiers, minerals
- Amino acids

#### Processing aids
- Enzymes, solvents
- Filter media, boiler water additives

#### Foods
- Fructose, dextrose, sucrose
- Whey, amino acids

#### Flavoring agents
- Natural and synthetic flavors
- Essential oils

#### Functional food ingredients
- Olestra, salatrim, high-oleic canola oil
- Diacylglycerol oil, lycopene, scFOS
FCC Monograph

- Standard for an individual food ingredient
- Major sections
  - Chemical Identity
  - Description, including function and packaging & storage (Informational ONLY)
  - Identification
  - Assay
  - Impurities – Inorganic & Organic
  - Specific Tests
  - Additional Information – Labeling, etc.
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Manufacturing Process
Physical Description
Solubility (General)
FCC Monograph

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  - Chemical Identity
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  - Identification
  - Assay
  - Impurities - Inorganic
  - Specific Tests
  - Additional Information – Labeling, etc.

Measure What’s Important!

Analytical Method(s) & Specifications
Gets tricky in some materials…functional tests vs. compositional tests.
FCC Monograph

- Standard for an individual food ingredient
- Major sections:
  - Chemical Identity
  - Description, including function and packaging & storage (Informational ONLY)
  - Identification
  - Assay
  - Impurities – Inorganic & Organic
  - Specific Tests
  - Additional Information – Labeling, etc.

Elemental Impurities (Pb, As, Hg, etc.)
Process Impurities; Contaminants; Related Compounds Controlled for Quality
Analytical Method(s) & Specifications
FCC Monograph

- Standard for an individual food ingredient
- Major sections
  - Chemical Identity
  - Description, including function and packaging & storage (Informational ONLY)
  - Identification
  - Assay
  - Impurities – Inorganic & Organic
  - Specific Tests
  - Additional Information – Labeling, etc.

What else matters? Functional tests; Quality tests; Important parameters for use

Analytical Method(s) & Specifications
**Astaxanthin Esters from *Haematococcus pluvialis***

First Published: FCC 7, Third Supplement

**Astaxanthin**

**Astaxanthin Esters**

**Astaxanthin Fatty Acid Esters**

(3,3’S)-3,3’-dihydroxy-β,β-carotene-4,4’-dione

**DESCRIPTION**

Astaxanthin Esters from *Haematococcus pluvialis* occurs as a dark red, viscous oil. It is the product of the fermentation of *Haematococcus pluvialis*, extracted with either super critical CO₂ or acetone. It is a complex mixture, primarily composed of lipids, with astaxanthin esterified with common edible fatty acids to form both mono- and diesters. Esterified astaxanthin is the primary carotenoid present and the approximate astaxanthin composition is: 75% monoester, 20% diester, and 5% free form astaxanthin. Astaxanthin Esters from *Haematococcus pluvialis* is soluble in n-hexane, acetone, and ether; partially soluble in alcohol; practically insoluble in water and hot water. Suitable antioxidants may be added.

**Function:** Source of astaxanthin

**Packaging and Storage:** Store in tight, light-resistant containers in a cool place.
**Example FCC Monograph**

**IDENTIFICATION**
- **EPA Content.** Fatty Acid Composition (Saturated, cis-Monounsaturated, and cis-Polyunsaturated) in Oils Containing Long Chain Polyunsaturated Fatty Acids, Appendix VII
  Analysis: Proceed as directed, then calculate the amount of EPA (eicosapentaenoic acid; C20:5 n-3) present as the percentage of total fatty acids. Acceptance criteria: NMT 1.0%.
- **Thin-Layer Chromatography.** Appendix II A
  Sample solution: 10 mg/mL in acetone
  Standard solution: 10 mg/mL of USP Astaxanthin Esters from *Haematococcus pluvialis* RS in acetone
  Adsorbent: 0.25-mm layer of chromatographic silica gel.
  [NOTE—Dry silica gel at 110°C for 1 h before use.]
  Developing solvent system: Hexane and acetone [70:30] Application volume: 5 μL
  Analysis: Develop the chromatogram in the Developing solvent system until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber and dry in a current of air.
  Acceptance criteria: The principal spots obtained from the Sample solution correspond in color, size, and Rf value to those obtained from the Standard solution.

**ASSAY**
- **Astaxanthin (Total).** [NOTE—Astaxanthin measured by this method is total astaxanthin, including free astaxanthin and both mono- and diesters.]
  Buffer solution: Dissolve 6.06 g of tris(hydroxymethyl)aminomethane in 750 mL of water, adjust with 1 M hydrochloric acid to a pH of 7.0, and dilute with water to 1000 mL.
  Solution A: 4 U/mL of cholesterol esterase² in Buffer solution. [NOTE—Prepare fresh daily.]
**Example FCC Monograph**

**IMPURITIES**

**Inorganic Impurities**

- **ARSENIC**, Elemental Impurities by ICP, Appendix IIIC
  
  **[NOTE—Alternatively, the arsenic content may be determined by the following method.]**
  
  Acceptance criteria: NMT 2.0 mg/kg
- **CADMIUM**, Elemental Impurities by ICP, Appendix IIIC
  
  Acceptance criteria: NMT 1.0 mg/kg
- **LEAD**, Elemental Impurities by ICP, Appendix IIIC
  
  **[NOTE—Alternatively, the lead content may be determined by the following method.]**

**Organic Impurities**

- **PHEOPHORBIDE CONTENT**
  
  Solution A: 50 mg/mL of sodium sulfate

  Solution B: Saturated solution of sodium sulfate

  Sample stock solution: Transfer 100 mg of the sample to a 10-mL test tube, add 10 mL of acetone, and dissolve with sonication. Quantitatively transfer this solution to a separatory funnel, rinsing the test tube three times with 10-mL portions of acetone and adding the rinsings to the funnel. Add 30 mL of ethyl ether to the separatory funnel, followed by 50 mL of Solution A. Mix the contents of the separatory funnel.

**SPECIFIC TESTS**

- **WATER**, Water Determination, Appendix IIB
  
  Acceptance criteria: NMT 1.0%

**OTHER REQUIREMENTS**

- **LABELING** Label to indicate the name of any added antioxidant.
FCC Identity Standards

- Similar…but different
- What are Identity Standards
  - NOT Monographs
  - Regulatory implications will differ
  - ADVISORY in nature
  - Guidance for users
    - Test methods; typical specifications
An FCC Identity Standard is an informational document designed to assist users in determining the identity or authenticity of a food ingredient or agricultural product for which a full monograph does not exist in the FCC. The FCC Identity Standard includes some of the same information that would be found in an FCC monograph, which may include synonyms, chemical formation, chemical formulas, chemical structures, production information, solubility details, packaging and storage instructions, and intended functions in food manufacture/processing. The FCC Identity Standard also notably includes multiple test methods and specifications under the header of Identification, similar to most FCC monographs. In the case of FCC Identity Standards, however, more test methods may be necessary to authenticate an ingredient, and wider specifications ranges may be included to account for variability in those types of food ingredients. Public data may be used, in part or in whole, to develop such specifications.
What is an FCC Identity Standard?

- A critically reviewed set of parameters developed intended to help users answer “Is this REALLY …?”
- Comprehensive Identification specifications (and methods) – MORE criteria for ID to account for natural sources of variation
- Helps users determine identity/authenticity – not a measure of quality
- Meant ONLY for ingredients that are NOT already the subject of an FCC monograph
- INFORMATIONAL and not required by FDA, etc.
Why do we need *FCC* Identity Standards?

- Address specific products with wide variability (natural) – honey, juices, spices, herbs, etc.
- A single standard of purity and quality may not make sense or be useful to all global stakeholders
- Authenticity difficult to determine – numerous tests may be available, but “specifications” may be lacking OR may be designed to describe a specific QUALITY of product instead of its IDENTIFICATION
FCC Standard Setting Process

Participants:
- Expert volunteers
- Industry
- Government
- Academia
- Labs
- Staff
USP Food Science Volunteers

- USP Food Ingredients Expert Committee
- USP Olive Oil Authenticity and Quality Expert Panel
- USP Honey Expert Panel
- USP Dietary Proteins Expert Panel
**FCC Standard Setting Process**

The **FCC Forum**
FCC Standard Setting Process

Key Points:

- Standards are drafted by staff and Expert Volunteers
- Two *FCC Forum* publications per year
  - June 30
  - December 31
- *FCC Forum* access is FREE online
- 90 Day public comment period
- Experts and staff address comments…
  - Ballot by Food Ingredients Expert Committee
  - Publication of final standard – Effective after 90 Days
  - Changes by comments? See the Commentary…
# FCC Publication Schedule

<table>
<thead>
<tr>
<th>FCC FORUM DATE</th>
<th>COMMENT PERIOD</th>
<th>TARGET FCC PUBLICATION</th>
<th>PUBLICATION DATE</th>
<th>PUBLICATION EFFECTIVE DATE</th>
</tr>
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Thank You

Empowering a healthy tomorrow