

## **Commentary**

### ***Food Chemicals Codex (FCC), Twelfth Edition, First Supplement***

23 October 2020

In accordance with the provisional Rules and Procedures of the 2020–2025 Council of Experts (CoE Rules), and except as provided in Section 9.02 *Accelerated Revision Processes*, USP publishes proposed revisions to the *Food Chemicals Codex (FCC)* for public review and comment in the *FCC Forum (FCCF)*, USP's venue for providing public notice and receiving public comment on an *FCC* proposed standard. After comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to effective status or be republished in *FCCF* for further notice and comment, in accordance with the CoE Rules. In cases when proposals advance to effective status, a summary of comments received and the FIEC's responses, as well as Expert Committee-initiated changes, are published in the *Commentary* section of the FoodChemicalsCodex.org website at the time the revision is published.

The *Commentary* is not part of the text of the monograph or general test or assay. Rather, it explains the basis of the FIEC's response to public comments. If there is a difference or conflict between the contents of the *Commentary* section and the monograph or general test or assay, the text of the monograph prevails. For further information, contact:

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**Comments were received or Expert Committee Changes were initiated for text regarding the following monographs proposed in for inclusion in the Food Chemicals Codex (FCC):**

- [Allulose](#)
- [Anise Oil](#)
- [Appendix XVI: Protein-Based Ingredients – Determination of Starch and Starch Degradation Products in Skim Milk Powder and Nonfat Dry Milk](#)
- [Butyl Isothiocyanate](#)
- [Camellia Seed \(Camellia oleifera\) Oil](#)
- [Cellulose Gum](#)
- [Citric Acid](#)
- [Citric and Fatty Acid Esters of Glycerol](#)
- [Jagua \(Genipin-Glycine\) Blue](#)
- [Ponceau 4R](#)
- [Rice Bran Oil](#)

**No Comments were received for text regarding the following monographs proposed for inclusion in the Food Chemicals Codex (FCC):**

- Allyl Butyrate
- Glyceryl Benehate
- Gibberellic Acid
- Potassium Gibberellate
- Sucralose

**Monograph/Section(s):** Allulose/Multiple Sections

**Expert Committee:** Food Ingredients

**No. of Commenters:** 2

**Comment Summary #1:** The commenter requested the title be amended from “Allulose” to “Allulose, Crystalline” to differentiate the subject of the standard from liquid products of commerce which are not represented by the proposed standard.

**Response:** Comment not incorporated. The title originally proposed is consistent with FCC nomenclature for similar ingredients.

**Comment Summary #2:** The commenter requested that the “relative retention time (RRT)” in the *Sample Note* under the *Assay* be changed to “retention time” to correct an error in the original proposal.

**Response:** Comment incorporated.

**Expert Committee-initiated Change #1:** The *Acceptance criteria* for *Lead* in *Inorganic Impurities* was changed from “NMT 0.1 mg/kg” to “NMT 1 mg/kg” to correct an error in the original proposal.

**Monograph/Section(s):** Anise Oil/Description

**Expert Committee:** Food Ingredients

**No. of Commenters:** 0

**Expert Committee-initiated Change #1:** The *Description* has been updated to provide clarification related to the sources of *Anise Oil*. Oils from *Pimpinella anisum* are obtained from the seeds (fruit) of an annual herb, while oils from *Illicium verum Hook* are obtained from the fruit of an evergreen tree.

**Monograph/Section(s):** Appendix XVI: Protein-Based Ingredients – Determination of Starch and Starch Degradation Products in Skim Milk Powder and Nonfat Dry Milk/Multiple Sections

**Expert Committee:** Food Ingredients

**No. of Commenters:** 0

**Expert Committee-initiated Change #1:** The *Acceptance criteria* for glucose in the hydrolyzed sample was changed from “NMT 0.10%” to “NMT 0.11%” to accommodate variation in sample and testing.

**Expert Committee-initiated Change #2:** “Materials failing to meet the criterion are suspected of adulteration” was changed to “Materials failing to meet above criterion are suspected of adulteration” to avoid confusion.

**Monograph/Section(s):** Butyl Isothiocyanate/Description

**Expert Committee:** Food Ingredients

**No. of Commenters:** 0

**Expert Committee-initiated Change #1:** The color and odor descriptors “ish” and “like” were removed from the *Description* because they add no additional information.

**Monograph/Section(s):** Camellia Seed (*Camellia oleifera*) Oil/Multiple Sections

**Expert Committee:** Food Ingredients

**No. of Commenters:** 0

**Expert Committee-initiated Change #1:** The monograph name was changed from “Camellia Seed Oil” to “Camellia Seed (*Camellia oleifera*) Oil” to represent the exact botanical source of oil represented by the monograph.

**Expert Committee-initiated Change #2:** The function “flavoring agent” was removed based on information that camellia seed oil has no flavor.

**Expert Committee-initiated Change #3:** The range of C18:1 was changed from “74-81%” to “74-87%” in the *Fatty Acid Composition in Identification* test based on additional information and data received.

**Expert Committee-initiated Change #4:** The range of refractive index was changed from “1.460-1.464” to “1.460-1.467” in *Specific Tests* based on additional information and data received.

**Monograph/Section(s):** Cellulose Gum/Description

**Expert Committee:** Food Ingredients

**No. of Commenters:** 0

**Expert Committee-initiated Change #1:** The color in the *Description* was changed from “white to cream” to “white to off-white” to more accurately reflect the product.

**Monograph/Section(s):** Citric Acid/Specific Tests

**Expert Committee:** Food Ingredients

**No. of Commenters:** 0

**Expert Committee-initiated Change #1:** The wording of multiple sections in the *Oxalate* test were updated to include instructions to prepare and analyze the standard solution in the same way as the sample solution. These instructions were inadvertently omitted from the original proposal.

**Monograph/Section(s):** Citric and Fatty Acid Esters of Glycerol

**Expert Committee:** Food Ingredients

**No. of Commenters:** 1

**Comment Summary #1:** The commenter requested harmonization in the sample preparation between the tests for *Total Fatty Acid*, *Total Citric Acid*, and *Total Glycerin* for ease of use.

**Response:** Comment not incorporated. This revision may be published in a future *FCC Forum* when sufficient supporting data is available.

**Monograph/Section(s):** Jagua (Genipin-Glycine) Blue/Assay

**Expert Committee:** Food Ingredients

**No. of Commenters:** 1

**Comment Summary #1:** The commenter asked about differences in the *Acceptance criteria* for the two tests under *Assay* and whether they represent measurement of the same compounds.

**Response:** The Expert Committee reviewed data submitted related to the *Acceptance criteria* for *Jagua (Genipin-Glycine) Blue Polymer* and *Total Color* and revised the *Acceptance criteria* for *Total Color* from “37-47%” to “25-50%” to reflect the relationship between the two parameters for samples reported.

**Monograph/Section(s):** Ponceau 4R/Multiple Sections

**Expert Committee:** Food Ingredients

**No. of Commenters:** 0

**Expert Committee-initiated Change #1:** The color in the *Description* was changed from “reddish” to “red” for clarification.

**Expert Committee-initiated Change #2:** The note “D needs to be expressed as a decimal and not a %” was added to the calculation for *Subsidiary Coloring Matters* for clarification.

**Expert Committee-initiated Change #3:** System suitability criteria originally referenced in the test for *Uncombined Intermediates and Products of Side Reactions* was added to *Subsidiary Coloring Matters* to avoid confusion.

**Expert Committee-initiated Change #4:** The maximum absorbance was changed from “505 nm” to “505-510 nm” in the *Identification* test based on additional information and data received.

**Expert Committee-initiated Change #5:** The formula weight was changed from “604.48” to “604.46” in the *Chemical Information* section to represent the exact chemical substances represented by the monograph.

**Monograph/Section(s):** Rice Bran Oil/Multiple Sections

**Expert Committee:** Food Ingredients

**No. of Commenters:** 0

**Expert Committee-initiated Change #1:** The *Acceptance criteria* in the *Fatty Acid Composition* under *Identification* were changed to align with those in CODEX-STAN 210–1999 (last revised in 2015).

**Expert Committee-initiated Change #2:** The *Organic Impurities* test and specification for *Hexane-Insoluble Matter* were removed because of insufficient information and data to support the requirements.