



**Commentary**  
***Food Chemicals Codex (FCC)***  
***Ninth Edition, First Supplement***

**September 2, 2014**

In accordance with USP's Rules and Procedures of the 2010-2015 Council of Experts, and except as provided in Section 8.01(e) Immediate Standards, USP publishes proposed revisions to the *Food Chemicals Codex (FCC)* for public review and comment in the *FCC Forum (FCCF)*, USP's journal for public notice and comment for *FCC*. After comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to official status or be republished in *FCCF* for further notice and comment, in accordance with the Rules and Procedures. In cases when proposals advance to official status without republication in *FCCF*, a summary of comments received and the FIEC's responses are published on the *Commentary* section of the USP 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 between the contents of the *Commentary* section and the monograph or general test or assay, the text of the monograph prevails. In case of a dispute or question of interpretation, the language of the monograph text, alone and independent of the *Commentary* prevails.

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**Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):**

**General Tests and Assays:**

- [Appendix XVIA, Nonprotein Nitrogen Determination for Skim Milk Powder and Nonfat Dry Milk](#)

**Monographs:**

- [Bacillus coagulans GBI-30, 6086](#)
- [Isobutyl Heptanoate](#)
- [Pomegranate Juice](#) (Identity Standard)
- [Stearyl Alcohol](#)

**No Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):**

**General Tests and Assays**

- Carbohydrate Authenticity Markers for Soluble (Instant) Coffee
- Optical (Specific Rotation)
- Lead Limit Test

**Monographs:**

- Allyl Disulfide
- Alpha-Amylcinnamyl Formate
- Benzenethiol
- Butyl Anthranilate
- Butyl Cinnamate
- Butyl Hexanoate
- Butyl Isothiocyanate
- Butyl Valerate
- 1,3-Butylene Glycol
- Calcium Pantothenate
- Cetylpyridinium Chloride
- Chromic Chloride
- Chromium Picolinate
- Cellulose Gum
- Food Starch, Unmodified
- Isobutyl Isobutyrate
- Oleic Acid
- Polyglycerol Polyricinoleic Acid
- Quercetin
- Rosemary Extract

**Monograph/Section(s):** Nonprotein Nitrogen Determination for Skim Milk Powder, Appendix XVIA/Multiple Sections  
**Expert Committee(s):** Monographs—Food Ingredients

**No. of Commenters:** 1

**Comment Summary #1:** The commenter requested replacing the term “diverse” when referring to the fifteen samples in the *Briefing* with the word “varied.” The commenter indicated that the term “diverse” implies significant differences; however, skim milk powder (SMP) is quite uniform globally due to the *Codex Alimentarius* definition.

**Response:** Comment not incorporated. The *Briefing* is not included in the final published version of this standard.

**Comment Summary #2:** The commenter requested replacing the phrase “detection capabilities” in reference to Table 1 with the phrase, “The relative amount of a nitrogen-rich adulterant (on a w/w basis) that when added increases the NPN content above the 95% confidence interval...”

**Response:** Comment partially incorporated. A footnote was added to the title of Table 1 to clarify what is meant by “detection capabilities.”

**Comment Summary #3:** The commenter indicated that the fifteen SMP samples referenced in the *Briefing* may not be sufficient to establish the acceptance criteria for the standard, and suggested adding to the standard information on the samples used in the study, including composition and origin.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to the standard upon the receipt of necessary supporting data.

**Comment Summary #4:** The commenter requested adding information on the fifteen samples used to establish the acceptance criteria, including their composition and origin.

**Response:** Comment not incorporated. The requested information is not included in *FCC* standards.

**Expert Committee-initiated Change #1:** The Expert Committee clarified the applicability of the standard to both skim milk powders and nonfat dry milks by adding the term “nonfat dry milks” throughout the standard, and adding a *Scope* section to explain the applicability of the standard to both types of milk powder.

**Monograph/Section(s):** *Bacillus coagulans* GBI-30, 6086/Multiple Sections

**Expert Committee(s):** Monographs—Food Ingredients

**No. of Commenters:** 1

### Assay

**Comment Summary #1:** The commenter suggested deleting the exact aliquots of the Peptone diluent to be dispensed from the instructions for preparing the Peptone diluent, in order to make the instructions less specific. This proposed change would provide users with flexibility and remove overly prescriptive wording.

**Response:** Comment incorporated.

**Comment Summary #2:** The commenter requested deleting the instructions to transfer the contents of one sterile bottle of Peptone diluent to the stomacher bag. Instead, the commenter suggested that the standard instruct users to add an amount of previously sterilized Peptone diluent to the sample for dilution. This proposed change would provide users with flexibility and remove overly prescriptive wording.

**Response:** Comment incorporated.

### ***Identification***

**Expert Committee-initiated Change #1:** The wording of the *Sample* section of the Nucleic Acid-Based Identification test was changed to clarify that the sample reagent must be dispensed into microcentrifuge tubes prior to suspending sample cells in the reagent. In addition, it was clarified that the cells from one single surface colony should be used in preparation of the Sample.

<b>Monograph/Section(s):</b>	Pomegranate Juice ( <i>FCC Identity Standard</i> ) / Multiple Sections
<b>Expert Committee(s):</b>	Monographs—Food Ingredients
<b>No. of Commenters:</b>	8

### ***General***

**Comment Summary #1:** The commenters requested that USP discontinue work on the proposed *FCC Identity Standard*, because some buyers could potentially require compliance with this *FCC Identity Standard* from their vendors as a condition of doing business. Although this document is explicitly described as voluntary, this would create a “de facto” standard which could create a barrier to international trade.

**Response:** Comment not incorporated. This document is intended to be a voluntary use document and, as such, is not a “de facto” standard or requirement.

**Comment Summary #2:** The commenters requested that USP discontinue work on the proposed *FCC Identity Standard*, because industry reference guidelines, such as the *Code of Practice* from the European Fruit Juice Association (AIJN), already exist for pomegranate juice and are commonly used in industry.

**Response:** Comment not incorporated. The existence of a separate voluntary use guidance document does not prohibit other scientific standards or guidelines from being recommended for any specific food ingredient. The *AIJN Code of Practice* was used as a source of background information in the development of this proposed *FCC Identity Standard*. Many of the analytical acceptance criteria in the proposed *FCC Identity Standard* are harmonized with the *AIJN Code of Practice* where independent data and information supported this harmonization.

**Comment Summary #3:** The commenters requested that USP discontinue work on the proposed *FCC Identity Standard*, because it presents a different compositional criteria for pomegranate juice than the *AIJN Code of Practice* referenced in Comment Summary #2.

**Response:** Comment not incorporated. The Expert Committee has adjusted some of the acceptance criteria within the proposed *FCC Identity Standard* to harmonize with the *AIJN Code of Practice* where independent supporting data and information were available. (See Expert Committee-initiated Change #1). The Expert Committee will consider future revisions to the proposed standard, upon the receipt of necessary supporting data related to specific acceptance criteria.

**Comment Summary #4:** The commenters requested that USP discontinue work on the proposed *FCC Identity Standard*, because the U.S. Food and Drug Administration already defines 100 percent pomegranate juice as 16° Brix.

**Response:** Comment not incorporated. The proposed *FCC Identity Standard* is not in conflict with the definition used by the U.S. Food and Drug Administration. Furthermore, this voluntary standard is intended for use internationally, not solely in the United States.

**Comment Summary #5:** The commenters requested that USP discontinue work on the proposed *FCC Identity Standard*, because they do not believe that the *FCC Identity Standard* will be sanctioned by the FDA and, as such, compliance or noncompliance would not be enforceable by the FDA or other regulatory agencies.

**Response:** Comment not incorporated. The proposed *FCC Identity Standard* is intended for voluntary use.

**Comment Summary #6:** The commenters requested that USP discontinue work on the proposed *FCC Identity Standard*, because the compositional parameters included in the proposal may not be representative of juices from all pomegranates, based on variation expected by growing conditions, geographical origin of the fruits, and differences in cultivars used. The commenters believe that the *FCC Identity Standard* could be misinterpreted as representing the composition of all pomegranate juices. Furthermore, the commenters believe that users might conclude that any product that falls within the compositional ranges included within the *FCC Identity Standard* is authentic pomegranate juice.

**Response:** Comment not incorporated. The introductory section to *FCC Identity Standards* in the *Food Chemicals Codex* explains that additional analyses may be necessary to verify the authenticity of pomegranate juice products. This voluntary use document is intended to assist users in determining the identity or authenticity of a food ingredient, not provide definitive authentication.

**Comment Summary #7:** The commenters requested that USP discontinue work on the proposed *FCC Identity Standard*, because the analytical methods pose multiple issues. The commenters indicated that the methods in the proposal may not be validated for pomegranate juice. Furthermore, there are authoritative sources of validated methods which would be more appropriate than the methods included in the proposed *FCC Identity Standard*, particularly those referenced by the Codex Alimentarius Commission in the *Codex General Standard for Fruit Juices and Nectars*. Finally, the commenters believe that there are errors and ambiguities that exist in the methods, as proposed.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to the proposed standard, upon the receipt of supporting data.

**Comment Summary #8:** The commenters requested that USP discontinue work on the proposed *FCC* Identity Standard, because some of the analytical methods included in the proposal are outdated do not correspond to the current state of knowledge in the industry.

**Response:** Comment not incorporated. The *Food Chemicals Codex* does allow the use of alternative analytical procedures under the policy described in the *General Provisions and Requirements Applying to Specifications, Tests, and Assays of the Food Chemicals Codex*. In addition, a specific reference to this policy was added to the *Identification* (see Expert Committee-initiated change #3). The Expert Committee will consider future revisions to the proposed standard, upon the receipt of supporting data.

**Comment Summary #9:** The commenters requested that USP discontinue work on the proposed *FCC* Identity Standard, because the proposal indicates that all data should be standardized to represent juice at 16° Brix, which is the Brix requirement for pomegranate juice in the United States. The commenters indicated that other countries have different (lower) Brix level requirements for pomegranate juice and pomegranate juice from concentrate. The commenters expressed concern that standardizing data to represent juice at 16° Brix could negatively impact juices from other countries where the Brix requirements are different.

**Response:** Comment not incorporated. This proposal is a voluntary use standard. The proposal explains that data gathered should be standardized to represent juice at 16° Brix in order to compare data gathered to the requirements of the proposed *FCC* Identity Standard. There is no indication in the proposal that only juices at 16° Brix are authentic or approved pomegranate juice.

**Comment Summary #10:** The commenters requested that USP discontinue work on the proposed *FCC* Identity Standard, because the ranges of acceptance criteria included in the proposal do not correspond to those established in the *AIJN Reference Guideline* for pomegranate juice. The commenters indicated that differences between the two documents will cause confusion in the juice industry and could result in authentic pomegranate juice being declared as adulterated.

**Response:** Comment not incorporated. The existence of a separate voluntary use guidance document does not prohibit other scientific standards or guidelines from being recommended for any specific food ingredient. The *AIJN Reference Guideline* was used as a source of background information in the development of this proposed *FCC* Identity Standard and many of the analytical acceptance criteria in the proposed *FCC* Identity Standard are harmonized with the *AIJN Reference Guideline* where independent data and information supported this harmonization. Users of each document must determine when to apply the different standards/specifications to their products. Additionally, the introductory section to *FCC* Identity Standards in the *Food Chemicals Codex* explains that additional analyses may be necessary to verify the authenticity of pomegranate juice products. This voluntary use document is intended to assist users in determining the identity or authenticity of a food ingredient, not provide definitive authentication.

**Comment Summary #11:** The commenters requested that USP discontinue work on the proposed *FCC* Identity Standard, because it may pose a barrier to international trade.

**Response:** Comment not incorporated. This proposed *FCC* Identity Standard is clearly described as a voluntary use standard. Voluntary standards exist in many industries and the decision of whether or not to comply with this proposal lies completely with *FCC* users.

**Comment Summary #12:** The commenters requested that USP discontinue work on the proposed *FCC* Identity Standard, because the values included in the proposal do not represent pomegranate juice from all countries that grow pomegranates and produce juice.

**Response:** Comment not incorporated. The Expert Committee did receive literature to support the commenters' claim; however, no specific revisions to the acceptance criteria within the proposed *FCC* Identity Standard were received from the commenters. Additionally, the literature provided addressed testing of varieties of pomegranates that are currently not sources of commercially available juices. The Expert Committee will consider future revisions to the proposed standard, upon the receipt of supporting data.

**Comment Summary #13:** The commenter requested that USP discontinue work on the proposed *FCC* Identity Standard, because some of the publicly available sources of data and information cited in the proposed standard may not represent the testing of authentic pomegranate juices. The commenters also expressed concern that these same literature sources may not include data from pomegranate juices produced over multiple growing seasons or from juices representative of all geographic regions that currently produce pomegranate juice.

**Response:** Comment not incorporated. The commenter supplied additional scientific literature to support this comment; however, the Expert Committee has harmonized several of the compositional requirements in the proposed standard with those utilized in the *AIJN Reference Guideline*, which has been positively referenced as an authoritative source of information by this commenter and others. (See Expert Committee-initiated Change #1.) The Expert Committee will consider future revisions to the proposed standard, upon the receipt of supporting data.

**Comment Summary #14:** The commenter suggested several changes to acceptance criteria within the *FCC* Identity Standard based on the commenter's experience in analyzing pomegranate juice products.

**Response:** Comment not incorporated. The Expert Committee has made similar changes to several acceptance criteria in an effort to harmonize several parameters with the *AIJN Code of Practice*. (See Expert Committee-initiated Change #1).

**Expert Committee-initiated Change #1:** The Expert Committee revised specifications for citric acid, malic acid, sorbitol, mannitol, potassium, and D-isocitric acid in order to harmonize with the *AIJN Code of Practice* referenced by several commenters.

### ***Description***

**Comment Summary #15:** The commenter requested clarification regarding the parts of the pomegranate fruits which should be used to make Pomegranate Juice, as described in the *Description* section. To harmonize with other standards, the commenter requested that the *Description* state that pomegranate juice "...is the juice obtained exclusively from the *edible parts of whole* pomegranate fruit..." [added text italicized]

**Response:** Comment incorporated.

### ***Packaging and Storage***

**Comment Summary #16:** The commenters indicated that the temperature included in the *Packaging and Storage* instructions in the draft proposal are not sufficiently low to ensure stability of pomegranate juice. The commenters requested that the storage temperature be lowered to support better stability of the ingredient.

**Response:** Comment partially incorporated. The Expert Committee changed the *Packaging and Storage* instructions. (See Expert Committee-initiated Change #2 below)

**Expert Committee-initiated Change #2:** The Expert Committee changed the *Packaging and Storage* instructions to indicate that the product should be stored "...frozen in tight, light-resistant containers for optimal stability." This change was made to recognize that the original storage temperature of 1°-5° may not provide a stable storage environment, depending on the concentration of the juice and the use (or not) of inert gas in the package.

### ***Identification, Introduction***

**Comment Summary #17:** The commenter indicated that the instructional note at the beginning of the *Identification* section needs clarification. As proposed the note indicates that data should be normalized to 16° Brix, but there is no mention of whether or not this value is corrected for acidity.

**Response:** Comment incorporated. The Expert Committee revised the note at the beginning of the *Identification* section of the monograph in order to clarify that the experimental data on pomegranate juice samples must be normalized to 16 ° Brix "without correction for acidity." Correction for acidity could lead to results which would not be represented by the acceptance criteria included in the *FCC Identity Standard*.

**Expert Committee-initiated Change #3:** The Expert Committee added wording to the note at the beginning of the *Identification* section to indicate that alternative analytical procedures may be used for sample analysis according to the *FCC* policy on *Alternative Analytical Procedures* described in the *General Provisions and Requirements Applying to Specifications, Tests, and Assays of the Food Chemicals Codex*. This change was made based on the number of commenters who asked about using procedures other than those included in the *FCC Identity Standard*.

### ***Identification, A. Sugar Profile***

**Comment Summary #18:** The commenter suggested that the *Sugar Profile* analysis could be performed with the same method outlined in the *Sorbitol and Mannitol* test.

**Response:** Comment not incorporated. The Expert Committee will consider future revisions to the proposed standard, upon the receipt of the necessary supporting data.

**Comment Summary #19:** The commenter requested that information be added to the *Sugar Profile* test to inform users that the use of some amino phase columns may result in the co-elution of mannitol and sorbitol with glucose, which requires users to subtract results for mannitol and sorbitol from the glucose result for accurate measurement of glucose.

**Response:** Comment incorporated. This information has been added to the footnote describing the *Column* used in the *Chromatographic system* for this test.

### ***Identification, B. Citric, Malic, and Tartaric Acid Content***

**Comment Summary #20:** The commenter requested that a note be added to the *Analysis* in the *Citric, Malic, and Tartaric Acid Content* test to clarify that analysts should be aware of the possibility of late eluting components, which can cause interferences in subsequent analyses with the *Chromatographic system* described.

**Response:** Comment not incorporated. This information is included in the *Analysis* section as proposed.

**Comment Summary #21:** The commenter requested that basic system suitability information be added to the *Chromatographic system* described in the *Citric, Malic, and Tartaric Acid Content* test.

**Response:** Comment incorporated. Additional information for determining system suitability has been added to the footnote on the *Column* in the *Chromatographic system* to indicate that fully resolved peaks should be obtained from a mixed solution of quinic and tartaric acids.

**Expert Committee-initiated Change #4:** The Expert Committee changed the title of one of the reagents described in the *Citric, Malic, and Tartaric Acid Content* test from *Diluent* to *Solution A* to clarify that the reagent is not consistently used as a diluent within the test.

### ***Identification, E. Carbon Stable Isotope Ratio***

**Comment Summary #22:** The commenter requested that a note be added to the *Combustion system* in the *Carbon Stable Isotope Ratio* test to indicate that a continuous flow variant of the system can be substituted for the specific system shown. This request was made to recognize that the system shown is not the only (or most modern) variant used.

**Response:** Comment incorporated.

**Expert Committee-initiated Change #5:** The Expert Committee revised the text of the footnote on the *Combustion system* figure in the *Carbon Stable Isotope Ratio* test in order to give proper attribution for the figure.

**Monograph/Section(s):** Stearyl Alcohol/Assay  
**Expert Committee(s):** Monographs—Food Ingredients  
**Expert Committee-initiated Change # 1:** The Expert Committee reinstated the *Acceptance Criteria* that was inadvertently deleted during the file conversion process.

**Monograph/Section(s):** Isobutyl Heptanoate/Specific tests  
**Expert Committee(s):** Monographs—Food Ingredients  
**Expert Committee-initiated Change # 1:** The Expert Committee added Specific Gravity specification of ~0.86 to the *Description* section, and deleted the Specific Gravity test from the *Specific Tests* section.