Commentary
Food Chemicals Codex (FCC), Thirteenth Edition

March 1, 2022

In accordance with the *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 without republication in the *FCCF*, a summary of comments received and the FIEC's responses are published in the *Commentary* section of the *FCC* microsite 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 (FCC):

- *Allulose, Syrup*
- *Appendix XIX—Olive Oil Guidance, Methods, and Applicable Resources*
- *Avocado Oil*
- *Hemp Seed Oil*
- *Hemp Seed Protein*
- *Steviol Glycosides*

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

- *Appendix V—Enzyme Assays, Phytase Activity*
- *Appendix V—Enzyme Assays, Trypsin Activity*
- *Appendix VII—Fats and Related Substances, Fatty Acid Composition (Saturated cis-Monounsaturated and cis-Polyunsaturated) In Oils Containing Long Chain Polyunsaturated Fatty Acids*
- *Black Pepper*
- *(+)-Camphor*
- *Copper Sulfate*
- *Jagua (Genipin-Glycine) Blue*
- *D-Tagatose*
- *Wheat Protein Isolate*
- *White Pepper*

Monograph/Section(s): Allulose, Syrup / Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: Commenter requested the addition of the term “flavor enhancer” to the *Function* section within the *Description* to more fully represent what the comment describes as the regulatory approval of the ingredient.
Response: Comment incorporated. The updated text reads: “Function: Sweetener; flavor enhancer” to expand upon the common uses of the ingredient.

Comment Summary #2: Commenter requested that “10 mM hydrochloric acid” be changed to “distilled water” in the *Sample solution* within the *Assay*. This proposed change represents current analytical practice for testing allulose, syrup samples and simplifies the procedure, eliminating the need to heat the solution and use an ion exchange resin to remove salts. The commenter supplied data to support the requested change.
Response: Comment incorporated. The updated text is found in *the Assay, Sample solution* and *Flow rate*. “Sample solution: Prepare a 5% (w/w) solids solution in water.” The rest of the text related to 10 mM hydrochloric acid is deleted.

Comment Summary #3: Commenter requested that the *Acceptance criteria* for the *Assay* be amended to include the phrase “on the dry basis” and read “90% - 110.0% of the labeled amount of allulose in the syrup on dry basis” based on common industry practice for reporting purity of the syrup on the dry basis.
Response: Comment incorporated to include the common industry practice of reporting the purity of the syrup on the dry basis. The updated text reads: “Acceptance criteria: 90% - 110.0% of the labeled amount of allulose in the syrup on the dry basis.”

Comment Summary #4: Commenter requested that the *Flow rate* in the *Assay* be changed from “0.5 mL/min” to “0.6 mL/min” to represent current analytical practice for testing allulose, syrup samples. The commenter supplied data to support the requested change.
Response: Comment incorporated. The test conditions are updated to reflect current analytical practice when testing liquid preparations of allulose.

Monograph/Section(s): Appendix XIX/ Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: Commenter requested an update to the text within *B.2.3 More than oil—additional components of extra virgin and virgin olive oils* related to *Phenolic compounds*. Specifically, the text that reads: “Polyphenols have been variously described as lowering risks of cancer, cardiovascular disease, and stroke, and acting as antimicrobial agents that protect low-density lipoprotein (LDL) cholesterol from oxidation.” The commenter indicated that underlined portion is incorrect; antimicrobial agents and protection of LDL cholesterol are not related. The commenter requested that this wording be changed to "...antimicrobial agents **and** protectors of low-density..."
Response: Comment incorporated to correct the statement. The updated text reads: “Polyphenols have been
variously described as lowering risks of cancer, cardiovascular disease, and stroke, and acting as antimicrobial agents and protectors of low-density lipoprotein (LDL) cholesterol from oxidation.”

Comment Summary #2: Commenter requested that Figure B.4 be updated to include dashed lines connecting the “Extra virgin category” and “Virgin category” with “Pomace olive oil” to indicate that pomace oil is sometimes blended with extra virgin and virgin olive oils to produce a commercial product.
Response: Comment incorporated. Figure B.4 has been updated to reflect the relationship between the “Extra virgin category” and the “Virgin category” with “Pomace olive oil”.

Comment Summary #3: Commenter requested a change to the following text in Section *5.1 Detection of olive oil products containing other grades or types of oil* for clarity: “Following the same rationale, Olive Oil, Refined sets a maximum content for those compounds that are produced during refining, e.g., trans-fatty acids, stigmastadienes, 2-MCPD fatty acid esters, 3-MCPD fatty acid esters, and glycidyl

esters." The comment suggested changing "Olive Oil, Refined" to "refined olive oil."
Response: Comment not incorporated. The text has been retained in order to match the term used in the standard of identity for "*Olive Oil, Refined* in *FCC."* However, a hyperlink was added to the text "Olive Oil, Refined" linking it to the identity standard for *Olive Oil, Refined* in *FCC* for clarification and ease of use and clarity.

Monograph/Section(s): Avocado Oil/ Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 4

Comment Summary #1: Commenter requested that the monograph title be changed from "Avocado Oil" to "Refined Avocado Oil". The commenter indicated that the refining process changes the chemical properties of the oil and hence the nutrients in the oil, making it important to distinguish the subject of the proposed standard from so-called virgin or unrefined oils.
Response: Comment not incorporated. The *Description* of this identity standard indicates it applies to refined avocado oil. Differentiating refined from some other undefined "grade" of avocado oil in the title might confuse users as various grading terms for avocado oil are not globally defined and appear to only be used for marketing purposes currently.

Comment Summary #2: Commenter requested changes to the *Acceptance criteria* in *Table 5* in the test for *Sterol Profile*. The commenter requested the *Acceptance criteria* for Δ-7-stigmastenol be changed from "NMT 3.5" to "NMT 1.0"; and Δ-7-avenasterol from "NMT 1.5" to "NMT 1.0". The commenter indicated that narrowing the specifications can prevent potential adulteration from high oleic oils including safflower, sunflower, or canola oils. The commenter referenced a publication.
Response: Comment not incorporated. The *Acceptance criteria* in the current proposal were determined after the evaluation of global data representing most avocado oils and not only those from certain locations. The publication referenced in the comment lacked sufficient detail to support changing the *Acceptance Criteria* and included a limited data set. Therefore, the proposed *Acceptance Criteria* is being retained, as narrowing the specifications could result in a standard that improperly excludes some authentic avocado oil products.

Comment Summary #3: Commenter requested the minimum *Acceptance criteria* for total sterols in the test for *Sterol Profile* be changed from "3000 mg/kg" to "3500 mg/kg". The commenter indicated that narrowing the specifications can prevent potential adulteration from high oleic oils including safflower, sunflower, or canola oils. The commenter referenced a publication to support their comment.
Response: Comment not incorporated. The *Acceptance criteria* in the current proposal were determined after the evaluation of global data representing most avocado oils and not only those from certain locations. The publication referenced in the comment lacked sufficient detail to support changing the *Acceptance Criteria*, and included a limited data set. Therefore, the proposed *Acceptance Criteria* is being retained, as narrowing the specifications could result in a standard that improperly excludes some authentic avocado oil products.

Comment Summary #4: Commenter requested the minimum *Acceptance criteria* for *Iodine Value* be changed from 72 to 80. The commenter indicated that narrowing the specifications can prevent potential adulteration from high oleic oils including safflower, sunflower, or canola oils.
Response: Comment not incorporated. The *Acceptance criteria* in the current proposal were determined after the evaluation of global data representing most avocado oils and not only those from certain locations. The commenter did not provide any supporting data for the comment. Therefore, the proposed *Acceptance criteria* is being retained, as narrowing the specifications could result in a standard that improperly excludes some authentic avocado oil products.

Monograph/Section(s): Hemp Seed Oil/ Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 7

Comment Summary #1: Commenter requested that the title of the monograph to be changed to "Hempseed Oil" to differentiate the product which is consumed, hempseed, from that which is planted, hemp seed.
Response: Comment not incorporated. **"**Hempseed oil" is listed in the synonym list and, as such, users can be search for and find the standard using the term in *FCC Online*. Also, "hemp seed" (as separate words) appears to be more commonly used to refer to the food ingredient based on a brief review of online product names.

Comment Summary #2: Commenters requested various changes to the *Description*. Four comments requested that additional information describing various approaches to hemp seed oil processing be added for clarification and one comment disagreed with "light green" being included in the list of acceptable colors for hemp seed oil.
Response: Comments partially incorporated. The updated *Description* incorporates additional processing techniques and reads: "Hemp Seed Oil is derived from the seeds of Cannabis sativa L. The oil is obtained via *a number of approaches including mechanical separation from the whole or parts of seeds using expeller pressing, suitable organic solvents, and or enzymes. It may be filtered and packaged directly as is or it and may undergo bleaching, winterization, and deodorization to produce refined hemp seed oil.* Hemp Seed Oil is clear, light green to light yellow." The underlined text incorporates edits based on the comments received that requested additional information related to hemp seed oil processing. The Expert Committee did not delete "light green" from the possible colors on the basis that the color appears to be accurate based on descriptions available for products of commerce.

Comment Summary #3: Commenters requested that the following additional *Function*s be added in the *Description* to fully represent potential uses for this food ingredient: carrier oil, food, culinary oil, nutritional fortification, and frying oil.
Response: Comments partially incorporated. The updated text reads: "*Function: Food; culinary ingredient; cooking oil; carrier oil; coating agent; stabilizer; thickener; emulsifier;*

texturizer." The "nutritional fortification" function was not added by the Expert Committee based on a lack of context and supporting information; "frying oil" was not included as it is already covered by the "cooking oil" function.

Comment Summary #4: Commenters requested various changes to the *Packaging and storage* information in the *Description* based on current practices by individual companies.
Response: Comments partially incorporated. The *Packaging and storage* section was updated from "Store in well-closed containers in a dry place avoiding excessive heat" to "Store in well-closed light-resistant containers in a cool, dry place." The new instructions incorporate the commenters' concerns that products be protected, in general, from extraneous material and exposure to heat and moisture using standardized *FCC* language from the *General Provisions and Requirements Applying to Specifications, Tests and Assays of the Food Chemicals Codex*. The suggestion to store the oil under nitrogen was not included because adding this requirement would lead to inconsistencies with other oil monographs and is not necessary if the oil is stored as directed. The comments requesting changes to the *Description* that are not based on standardized *FCC* provisions have not been incorporated.

Comment Summary #5: Commenters indicated that the proposed test used for *Fatty Acid Composition*, AOCS Ce 1h-05, was unknown to them. Commenters stated that USP should not finalize the standard with the proposed *Acceptance criteria* until more data are available using the referenced analytical method. Commenters stated that the proposed values do not match profiles using other industry methods but did not provide a reference.
Response: Comments not incorporated. The *Acceptance criteria* ranges listed in the proposal were determined by analysis of commercially available samples and reviewing the ranges listed in a GRAS Notice that received a no objection letter from FDA. The commenters did not supply supporting data for any alternate limits.

Comment Summary #6: Commenters indicated that the proposed test used for *Sterol Profile* was unknown to them. Commentors stated that USP should not finalize the standard with the proposed *Acceptance criteria* until more data are available using the referenced method. Commentors stated this test method is not used in their industry.
Response: Comments not incorporated. The *Acceptance criteria* ranges listed in the proposal were determined by analysis of commercially available samples. The test method is widely used within the fats and oils industry and is listed within the Codex Alimentarius CXS-210, Standard for Named Vegetable Oils.

Comment Summary #7: Commenters requested separate changes to the *Acceptance criteria* for all the *Inorganic Impurities* (*Arsenic*, *Cadmium*, *Lead*, and *Mercury*). The first comment requested that *Acceptance criteria* for *Arsenic* and *Cadmium* be lowered from "NMT 1 mg/kg" to "NMT 0.2 mg/kg"; that *Lead* be lowered from "NMT 1 mg/kg" to "NMT 0.5 mg/kg"; and that the test and limit for *Mercury* be removed. The second comment requested that *Acceptance criteria* for all *Inorganic Impurities* be lowered and include kilograms of body weight (kg bw) as follows: *Arsenic* from "NMT 1 mg/kg" to "NMT 0.14

µg arsenic and its salts and derivatives/kg bw"; *Cadmium* from "NMT 1 mg/kg" to "NMT 0.09 µg cadmium/kg bw"; *Lead* from "NMT 1 mg/kg" to "NMT 0.29 µg lead/kg bw"; and *Mercury* from "NMT 0.1 mg/kg" to "NMT 0.29 µg mercury and its salts and derivatives/kg bw."

Response: Comments not incorporated. The *Acceptance criteria* are based in part on information supplied to support a GRAS notice that received a no objection letter from FDA, and because data for commercially available products was not submitted to show the requested limits are representative of products of commerce. Recommendations to include body weight are not ingredient specifications. These would be intake recommendations and, as such , they are inappropriate in this context. The Expert Committee will consider revising these *Acceptance criteria* in a future *FCC Forum* if supporting data are provided. if supporting data are provided.

Comment Summary #8: Commenters requested changes to the *Acceptance criteria* in the test for *Free Fatty Acids*. Three comments requested that the *Acceptance criteria* be raised from "NMT 1%" to "NMT 2%" on the basis that most hemp seed oils are cold pressed and filtered, so it is possible that freshly pressed oil is at or slightly greater than 1% free fatty acids. One comment requested that the *Acceptance criteria* be changed from "NMT 1%" to ">1%" on the basis that a true cold pressed oil is often above 1% FFA.

Response: Comments partially incorporated. The *Acceptance criteria* for *Free Fatty Acids* is changed to "NMT 2%." The Expert Committee did not agree with setting the *Acceptance criteria* at ">1%" as it would allow for higher FFA values which could lead to inclusion of low-quality oils.

Comment Summary #9: Commenter requested that the *Acceptance criteria* for *Total THC* in the test for *THC and CBD Content* be changed from "NMT 10 mg/kg" to "NMT 3,000 mg/kg" on the basis of the commenter's belief that US regulations allow 3,000 mg/kg THC in hemp.

Response: Comment not incorporated. The *Acceptance criteria* is consistent with certain global regulations for the food ingredient and is also consistent with levels in commercially available food ingredients.

Comment Summary #10: Commenter requested that the *Acceptance criteria* for *Total CBD* in the test for *THC and CBD Content* be changed from "NMT 75 mg/kg" to at least "NMT 200 mg/kg" on the basis that all hemp varieties produce CBD at levels 20 times higher than THC. Data from commercially available food ingredients was not supplied to support the comment.

Response: Comment not incorporated. The *Acceptance criteria* is consistent with available product data, certain global product requirements, and information supplied by stakeholders.

Comment Summary #11: Commenter requested that USP not finalize *Acceptance criteria* for *Total CBD* in the test for *THC and CBD Content* until more data on levels of CBD in hemp seeds and hemp seed products are available and best practices are established within the industry.

Response: Comment not incorporated. The *Acceptance criteria* is based on available product data, certain global product requirements and information supplied by stakeholders. The Expert Committee recognized the need to limit contamination of the food ingredient from non-seed plant parts, which give rise to CBD in the seed oil. The Expert Committee may consider revision of this *Acceptance criteria* in a future *FCC Forum* if additional data and information are made available.

EC-Initiated Change #1: The Expert Committee made the following changes to include revise instructions for preparing the *Standard mix stock solution* in the test for *THC and CBD Content* by changing "cannabidiol (CBD)" to "USP Cannabidiol Solution RS" and by changing "(−)-Δ^9-tetrahydrocannabinol (Δ^9-THC or THC)" to "USP Δ^9-Tetrahydrocannabinol RS (Δ^9-THC or THC)" to provide specific reference standards.
EC-Initiated Change #2: Change *footnote 6* from: "Use commercially available 1 mg/mL solutions of catalog numbers C-144, C-045, T-005, and T-093, from Sigma Aldrich, or equivalent" to: "Use commercially available 1 mg/mL solutions of catalog numbers C-144 and T-005, from Sigma Aldrich, or equivalent."
EC-Initiated Change #3: Change the *Analyte* name in *Table 5* from: "(−)-Δ^9-Tetrahydrocannabinol (Δ^9-THC or THC)" to "Δ^9-Tetrahydrocannabinol (Δ^9-THC or THC)" to align with the USP RS name.

Monograph/Section(s): **Hemp Seed Protein**
Expert Committee: **Food Ingredients**
No. of Commenters: **7**

Comment Summary #1: Commenter requested that USP consider another name for the monograph because the subject of the hemp seed protein monograph is a defatted meal that has not undergone steps to a concentrate protein. The commenter indicated their opinion that the current title might more accurately refer to a concentrated protein. The commenter did not provide a specific alternative title for consideration.
Response: Comment not incorporated. Hemp seed protein is a common name used in industry for the ingredient described in the proposal. The *Description* clarifies that concentrated proteins are not represented by this monograph.

Comment Summary #2: Commenter requested that the title of the monograph to be changed to "Hempseed Protein" to differentiate the product, which is consumed, hempseed, from that which is planted, hemp seed.
Response: Comment not incorporated. **"**Hempseed" is listed in the synonym list and, as such, users can search for and find the standard using the term in *FCC Online*. Also, "hemp seed" (as separate words) is commonly used to refer to the food ingredient based on a brief review of online product names.

Comment Summary #3: Commenters requested changes to the monograph synonym list. Changes were proposed to the following synonyms: "Hempseed cake" and "Hempseed flour" to be changed to "Hemp seed cake" and "Hemp seed flour",

respectively. Commenters additionally requested the inclusion of the following synonyms in the list: “*Cannabis sativa* seed protein”, “*Cannabis sativa* seed flour”, “Hemp seed meal”, and “Hemp seed powder”.
Response: Comments incorporated to reflect commonly used synonyms. “Hempseed cake” and “Hempseed flour” were revised to “Hemp seed cake” and “Hemp seed flour”, respectively. The terms “*Cannabis sativa* seed protein”, “*Cannabis sativa* seed flour”, “Hemp seed meal”, and “Hemp seed powder” were added to the list of synonyms.
Comment Summary #4: Commenters requested that the following additional *Function*s be added in the *Description* to fully represent potential uses for this food ingredient: fiber supplement, coating agent, stabilizer, thickener, emulsifier, texturizer, and whipping protein.
Response: Comment not incorporated. The information supporting a FDA GRAS notice that received a no objection letter from FDA, and provided supporting information for this monograph only includes uses involving nutritional fortifications which are represented by the original text.

Comment Summary #5: Commenters requested various changes to the *Packaging and storage* information in the *Description* based on current practices in individual companies related to minimizing exposure to light, air and temperature extremes.
Response: Comments partially incorporated. The *Packaging and storage* section was updated from “Store in well-closed containers in a dry place avoiding excessive heat” to “Store in well-closed light-resistant containers in a cool, dry place” in order to incorporate current industry practices to minimize exposure to light. The new instructions incorporate the commenters’ concerns that products be protected, in general, from extraneous material and exposure to light, heat, and moisture using standardized *FCC* language from the *General Provisions and Requirements Applying to Specifications, Tests and Assays of the Food Chemicals Codex.* The comments requesting changes to the *Description* that are not based on standardized *FCC* provisions have not been incorporated.

Comment Summary #6: Commenter indicated that the following information in the *Description* is not comprehensive: "The protein is obtained using a mechanical cleaning and cold-pressing process to separate the oil followed by milling and sifting to achieve the desired particle size." The commenter stated that there are other non-mechanical methods to produce this product, but no further details or data were supplied.
Response: Comment not incorporated. The manufacturing information included in the *Description* was based on information supporting an FDA GRAS notice that received a no objection letter from FDA as well as manufacturing details supplied by a stakeholder.

Comment Summary #7: Commenter indicated hemp seed protein manufactured from shelled seeds may be a cream-colored material instead of light-green (light-green being

the color provided in the *Description*). The commenter did not request a specific change to the text based on this observation.
Response: Comment not incorporated. The color is based on products used to support a GRAS notice that received a no objection letter from FDA and other publicly available documents containing product descriptions.

Comment Summary #8: Commenters indicated that the *Acceptance criteria* in the test for *Amino Acid Composition* do not match samples of hemp seed protein analyzed by a variety of publicly available analytical methods. The comments suggested delaying implementation of the method and specifications until the industry gathers comprehensive data using the prescribed analytical method. No data were provided by the commenters.
Response: Comments not incorporated. The current Acceptance criteria is supported by data Additional revisions may be considered upon receipt of supporting data.

Comment Summary #9: Commenters indicated that it is difficult to find third party, USDA-certified laboratories capable of performing the *Peptide Identification* analysis. One comment requested replacing the proposed analytical method with a technique more commonly used for peptide mapping, such as reversed-phase liquid chromatography with UV detection.
Response: Comments partially incorporated. The Expert Committee recognized the use of peptide mapping as a means of identifying plant-based proteins is an emerging technology with limited availability. The Expert Committee revised *Peptide Identification* by adding the following note after the title of the test: "[NOTE – While not a requirement for this monograph, users interested in fraud detection may use *Identification B. Peptide Identification* method and specification.]"

Comment Summary #10: Commenters requested separate changes to the *Acceptance criteria* for all the *Inorganic impurities (Arsenic, Cadmium, Lead, and Mercury)*. The first comment requested that the *Acceptance criteria* for *Arsenic* and *Cadmium* be lowered from "NMT 1 mg/kg" to "NMT 0.2 mg/kg"; that *Lead* be lowered from "NMT 1 mg/kg" to "NMT 0.5 mg/kg"; and that the test and limit for *Mercury* be removed. The second comment requested that *Acceptance criteria* for all *Inorganic Impurities* be lowered and include kilograms of body weight (kg bw) as follows: *Arsenic* from "NMT 1 mg/kg" to "NMT 0.14 µg arsenic and its salts and derivatives/kg bw"; *Cadmium* from "NMT 1 mg/kg" to "NMT 0.09 µg cadmium/kg bw"; *Lead* from "NMT 1 mg/kg" to "NMT 0.29 µg lead/kg bw"; and Mercury from "NMT 1 mg/kg" to "NMT 0.29 µg mercury and its salts and derivatives/kg bw."
Response: Comments not incorporated. The *Acceptance criteria* are based on information supplied to support a GRAS notice that received a no objection letter from FDA. Additionally, no data for commercially available products was submitted by the commenters to show that the requested limits are representative of products of commerce. Recommendations to include body weight are not ingredient specifications, they are intake recommendations and are inappropriate in this context. As data were

not made available to support lowering any of these limits, the limits are not being revised at this time. The Expert Committee will consider revising these *Acceptance criteria* in a future *FCC Forum* if supporting data are provided.

Comment Summary #11: Commenters requested various changes to the *Acceptance criteria* in the test for *Ash (Total).* Two comments requested that the *Acceptance criteria* be changed from "NMT 9%" to "NMT 15%"; the third comment requested that it be changed to a higher limit such as "NMT 13%" or "NMT 15%" to represent levels that may occur when older seeds are used to manufacture the product. No data were provided by the commenters.
Response: Comments not incorporated. The commenters did not supply supporting data to support the proposed changes.

Comment Summary #12: Commenter indicated that an *Acceptance criteria* of "90% to 110% of labelled amount" in the test for *Protein* is not appropriate on the basis that the current standard for Nutritional Facts panels on foods allows a 20% variance, not 10%. The commenter did not request a specific change to the text based on this observation.
Response: Comment not incorporated. The *Acceptance criteria* is based on technical variance and is not relevant to allowed variance of Nutrition Facts on product labels.

Comment Summary #13: Commenter requested that the *Acceptance criteria* in the test for *Fat* be changed from "NMT 18%" to either "NMT 25%" or "NMT 30%". Supporting product data were provided with the comment
Response: Comment partially incorporated. The *Acceptance criteria* was revised to "NMT 25%" based on data on products of commerce that had fat% of 17-23%.

Comment Summary #14: Commenter requested that the *Acceptance criteria* for *Total THC* in the test for *THC and CBD Content* be changed from "NMT 10 mg/kg" to "NMT 3,000 mg/kg" on the basis that "Canada is at 10 ppm whereas the USA is already 3,000, 300 times higher."
Response: Comment not incorporated. The *Acceptance criteria* is consistent with certain global regulations and is also consistent with levels in commercially available food ingredients.

Comment Summary #15: Commenter requested that the *Acceptance criteria* for *Total CBD* in the test for *THC and CBD Content* be changed from "NMT 75 mg/kg" to at least "NMT 200 mg/kg" on the basis that all hemp varieties produce CBD at levels 20 times higher than THC.
Response: Comment not incorporated. The *Acceptance criteria* is consistent with available product data, certain global product requirements and information on *Acceptance criteria* supplied by stakeholders. Further, data from commercially available food ingredients was not supplied to support the comment.

Comment Summary #16: Commenter requested that USP not finalize *Acceptance criteria* for *Total CBD* in the test for *THC and CBD Content* until more data on levels of

CBD in hemp seeds and hemp seed products are available and best practices are established within the industry.
Response: Comment not incorporated. The *Acceptance criteria* is consistent with available product data, certain global product requirements and information supplied by stakeholders. The Expert Committee recognized the need to limit contamination of the food ingredient from non-seed plant parts, which give rise to CBD in the hemp seed protein. The Expert Committee may consider revision of this *Acceptance criteria* in a future *FCC Forum* if additional data and information are made available.

EC-Initiated Change #1: The Expert Committee revised the *Acceptance criteria* in the test for *Amino Acid Composition* based on data acquired through additional testing. The following revisions to limits were made: Alanine minimum from 4.53% to 4.48%; Arginine maximum from 12.75% to 12.92%; Glutamic acid minimum from 18.48% to 18.10%; Glycine maximum from 4.76% to 4.82%; Histidine maximum from 2.89% to 2.93%; Isoleucine minimum and maximum from 3.82% and 4.15% to 3.68% and 4.43%, respectively; Lysine minimum from 3.77% to 3.68%; Phenylalanine maximum from 4.93% to 4.99%; Proline maximum from 4.33% to 4.34%; Serine minimum and maximum from 4.95% and 5.73% to 4.68% and 5.81%, respectively; Threonine minimum from 3.42% to 3.40%; Tyrosine maximum from 3.78% to 3.85%; and Valine minimum and maximum from 4.67% and 5.26% to 4.55% and 5.58%, respectively.
EC-Initiated Change #2: The Expert Committee made the following changes to include revise instructions for preparing the *Standard mix stock solution* in the test for *THC and CBD Content* by changing “cannabidiol (CBD)” to “USP Cannabidiol Solution RS” and by changing “(−)-Δ^9-tetrahydrocannabinol (Δ^9-THC or THC)” to “USP Δ^9-Tetrahydrocannabinol RS (Δ^9-THC or THC)” to provide specific reference standards.
EC-Initiated Change #3: Change *footnote 11* from: “Use commercially available 1 mg/mL solutions of catalog numbers C-144, C-045, T-005, and T-093, from Sigma Aldrich, or equivalent” to: “Use commercially available 1 mg/mL solutions of catalog numbers C-144 and T-005, from Sigma Aldrich, or equivalent.”
EC-Initiated Change #4: Change the *Analyte* name in *Table 5* from: “(−)-Δ^9-Tetrahydrocannabinol (Δ^9-THC or THC)” to “Δ^9-Tetrahydrocannabinol (Δ^9-THC or THC)” to align with the USP RS name.

Monograph/Section(s): Steviol Glycosides/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 6

Comment Summary #1: Commenters requested the addition of more detailed manufacturing information in the *Description*. The commenters specifically requested that the section be revised to align with the most recent Joint FAO/WHO Expert Committee on Food Additives (JECFA) monograph.
Response: Comment not incorporated. The current *Description* already includes the key information describing relevant processing steps. The proposed revisions are not required to appropriately describe the subject of the monograph.

Comment Summary #2: Commenter requested that a Note be added regarding the preparation of the *Standard solutions* in *Method 1* of the *Assay*. The proposed wording of the Note was supplied by the commenter: "Steviol glycosides are hygroscopic. Equilibrate standards as instructed in the sample preparation. Determine the water content using the Water (Karl Fischer) method, or equivalent, at time of use. Alternatively, an unopened and sealed reference standard with moisture value provided on the Certificate of Analysis may be used without equilibration." No data were provided by the commenter.
Response: Comment not incorporated. None of the data reviewed during the monograph revision process demonstrated the necessity for the steps indicated in the proposed Note.

Comment Summary #3: Commenter requested a revision to the column length from "250 mm" to "150 mm" in the *Chromatographic system* for *Method 1* of the *Assay*. The example column referenced in the applicable footnote is 150 mm in length and this column length represents what is currently used for this analysis.
Response: Comment incorporated. The column with a length of 150 mm was used for method development and validation. The typo "250 mm" is corrected to "150 mm".

Comment Summary #4: Commenter requested a revision to the *Suitability requirements* in *Method 1* of the *Assay*. The commenter specifically requested changing the *Resolution* from "NLT 1.3 between the rebaudioside A and stevioside peaks" to "NLT 1.3 for major steviol glycosides peaks of interest" in order to allow users to prepare system suitability solutions that best align with their specific product (or application), including products that do not contain rebaudioside A and stevioside.
Response: Comment not incorporated. The *System suitability* requirements must be met to demonstrate that a chromatograph is fit for the analytical purpose on the day of analysis, regardless of the composition of specific samples being analyzed. The revision proposed by the commenter would result in less specific suitability criteria and may not properly demonstrate the suitability of the chromatographic equipment.

Comment Summary #5: Commenter requested that the *System suitability solution* and *Standard solutions* in *Method 1* of the *Assay* be revised such that the solutions not be required to contain rebaudioside A and stevioside. The commenter requested that both sections be changed to indicate that users should "Include appropriate steviol glycoside standards to meet the system suitability requirements" in order to allow users to prepare solutions that best align with their specific product (or application), including products that do not contain rebaudioside A and stevioside.
Response: Comment partially incorporated. The Expert Committee removed the following statement from *Standard solutions:* "All *Standard solutions* must include rebaudioside A and stevioside" in recognition that these standards would not be needed to measure steviol glycosides not present in the sample material. The Expert Committee did not incorporate the comment for the *System suitability solution* because system suitability is required to demonstrate that a chromatograph is fit for the analytical purpose on the day of analysis, regardless of the composition of specific samples being analyzed.

Comment Summary #6: Commenter requested addition of “approximate” to the *Relative Retention Times* in *Table 2* on the basis that relative retention times will differ slightly between specific instruments and columns.
Response: Comment incorporated based on the rationale supplied by the commenter.