



Commentary

Food Chemicals Codex (FCC), 3rd Supplement to the Thirteenth Edition

September 1, 2023

In accordance with the *Rules and Procedures of the 2020-2025 Council of Experts (CoE Rules)*, 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 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 Forum (FCC Forum):

- [Pea Protein](#)
- [Rice Protein](#)
- [Taurine](#)

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

- Anisyl Propionate
- Calcium Cyclamate
- Choline Chloride
- Hemp Seed Oil
- Isobutyl Alcohol
- Lycopene from *Blakeslea trispora*
- Lycopene, Synthetic
- Meso-Zeaxanthin
- Moroccan Argan Oil
- Orange Oil, Cold-Pressed
- Phytic Acid Solution
- Polyvinyl Acetate
- L-Theanine
- L-Tyrosine

Monograph/Section(s): Pea Protein
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: A commenter requested revising the limit of the test for *Lipid (Fat)* to NMT 12% from the proposed NMT 10% due to challenges for firms to meet the level from a processing and technology perspective.

Response: Comment incorporated. Data was received supporting the increase in the limit for *Lipid (Fat)* to NMT 12%.

Comment Summary #2: A commenter requested removal of the minimum and maximum ranges for amino acids in the test, *Amino Acid Composition*.

Response: Comment not incorporated. Amino acid ranges are important parameters to help substantiate the Identification of protein ingredients. However, the commentor provided data to support the widening of ranges in the test, *Amino Acid Composition*. The proposed changes are described under EC-Initiated Change #1 below.

Comment Summary #3: A commenter requested lowering the *Acceptance criteria* in the test for *Protein* content by *Nitrogen Determination* from NLT 80% to NLT 50% based on products available on the market and to allow for flexibility and inclusion of pea

protein ingredients that are extruded or texturized. The commentor provided data to support the revision.

Response: Comment partially incorporated. The commentor provided information and data on Pea protein products available on the market with protein content ranging from 55% to 84% calculated on the dried basis, therefore, the Expert Committee agreed to revise the *Acceptance criteria* to “NLT 55% calculated on the dried basis.”

EC-initiated change #1: The Expert Committee revised the *Acceptance criteria* in the test for *Amino Acid Composition* based on data acquired from a commenter and third-party laboratory data. The Expert Committee stated that the values should be reported to one decimal place due limitations in method to accurately report to two decimal places. The following revisions to limits were made: Alanine minimum and maximum from 3.77% and 4.47% to 3.7% and 4.5%, respectively; Arginine minimum and maximum from 8.37% and 10.23% to 8.2% and 10.3%, respectively; Aspartic acid minimum and maximum from 9.92% and 11.43% to 9.7% and 12.3%, respectively; Cystine minimum and maximum from 0.33% and 0.72% to 0.1% and 1.5%, respectively; Glutamic acid minimum and maximum from 14.37% and 17.78% to 14.3% and 18.6%, respectively; Glycine minimum and maximum from 4.08% and 4.81% to 3.4% and 4.9%, respectively; Histidine minimum and maximum from 1.50% and 9.62% to 0.4% and 9.7%, respectively; Isoleucine minimum and maximum from 4.70% and 5.05% to 4.4% and 5.4%, respectively; Leucine minimum and maximum from 7.83% and 8.73% to 7.6% and 9.2%, respectively; Lysine minimum and maximum from 5.67% and 7.76% to 5.6% and 8.6%, respectively; Methionine minimum and maximum from 0.79% and 1.06% to 0.7% and 1.2%, respectively; Phenylalanine minimum and maximum from 4.71% and 7.02% to 4.7% and 7.1%, respectively; Proline minimum and maximum from 3.97% and 4.63% to 3.9% and 4.8%, respectively; Serine minimum and maximum from 5.30% and 5.61% to 4.1% and 6.3%, respectively; Threonine minimum and maximum from 3.02% and 4.09% to 3.0% and 4.1%, respectively; Tyrosine minimum and maximum from 3.68% and 4.67% to 3.3% and 4.8%, respectively; Valine minimum and maximum from 4.83% and 5.48% to 4.8% and 5.5%, respectively.

Monograph/Section(s): Rice Protein
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: A commenter requested removing *Standard solution B* and *Standard solution C* in *Identification A* as they were prepared but not used in the monograph.

Response: Comment incorporated. *Standard solution B* and *Standard solution C* in *Identification A* were used to establish linearity curve for each amino acid in the method validation. Since the linearity is established, there is no need to repeat it in *Identification A*.

EC-initiated change #1: The Expert Committee revised the *Acceptance criteria* in the test for *Amino Acid Composition* based on third-party laboratory data. The Expert Committee stated that the values should be reported to one decimal place due limitations in method to accurately report to two decimal places. The following revisions

to limits were made: Alanine minimum and maximum from 5.79% and 6.00% to 5.7% and 6.0%, respectively; Arginine minimum and maximum from 8.04% and 8.58% to 8.0% and 8.6%, respectively; Aspartic acid minimum and maximum from 8.86% and 9.28% to 8.8% and 9.3%, respectively; Cystine minimum and maximum from 1.11% and 1.39% to 1.1% and 1.4%, respectively; Glutamic acid minimum and maximum from 18.81% and 19.57% to 18.8% and 19.6%, respectively; Glycine minimum and maximum from 4.48% and 4.70% to 4.4% and 4.7%, respectively; Histidine minimum and maximum from 2.13% and 2.41% to 2.1% and 2.5%, respectively; Isoleucine minimum and maximum from 4.10% and 4.35% to 4.1% and 4.4%, respectively; Leucine minimum and maximum from 8.43% and 8.76% to 8.4% and 8.8%, respectively; Lysine minimum and maximum from 2.98% and 3.80% to 2.9% and 3.8%, respectively; Methionine minimum and maximum from 2.07% and 2.59% to 2.0% and 2.6%, respectively; Phenylalanine minimum and maximum from 5.87% and 6.07% to 5.8% and 6.1%, respectively; Proline minimum and maximum from 4.62% and 4.77% to 4.6% and 4.8%, respectively; Serine minimum and maximum from 4.99% and 5.25% to 4.9% and 5.3%, respectively; Threonine minimum and maximum from 3.41% and 3.60% to 3.4% and 3.6%, respectively; Tyrosine minimum and maximum from 5.34% and 5.56% to 5.3% and 5.6%, respectively; Valine minimum and maximum from 6.02% and 6.25% to 6.0% and 6.3%, respectively.

Monograph/Section(s): Taurine
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: A commenter requested declining the modernization of *Related Substances* test which was to replace TLC with HPLC-ELSD. The commenter stated that the ELSD detector was not suitable to quantify low-content unspecified impurities.

Response: Comment incorporated. The stability of the ELSD system is crucial for successful operation. Achieving this stability requires a high level of experience, presenting a challenge to stakeholders.