COMMENTARY—Food Chemicals Codex (FCC)
Seventh Edition, Third Supplement
August 26, 2011

In accordance with USP's Rules and Procedures of the 2010-2015 Council of Experts (Rules), USP publishes all proposed revisions to the *Food Chemicals Codex (FCC)* for public review and comment in the *FCC Forum* (*FCCF).* The *FCCF* is USP's free online journal for providing notice and receiving public comment on *FCC* standards. After public comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to effective status and be published in *FCC* or republished on the *FCCF* website for further notice and public comment in accordance with USP's Rules. When a proposed revision advances to effective status and is published in *FCC*, a summary of all comments received and the FIEC's responses are posted in the *Commentary* section of the USP website (www.usp.org).

The *Commentary* section below 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 content 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* section prevails.

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No Comments were received for the following proposals:

Solutions and Indicators
Test Solutions and Other Reagents

Monographs
(+)-Dihydrocarvone
(-)-Menthyl Acetate
1,3-Propanediol
2-Tridecenal
Alitame

No comments were received for the following proposals (continued):

Monographs *(continued)*
Appendix II – Physical Tests and Determinations
Appendix III –Chemical Tests and Determinations
Appendix VII – Fats and Related Substances
Appendix VIII – Oleoresins
Appendix XIV – Markers for Authenticity Testing
Astaxanthin Esters From Haematococcus Pluvialis
Balsam Peru Oil
Bentonite
Beta Glucan from Baker's Yeast (Saccharomyces Cerevisiae)
Brown
Cholic Acid
Citric and Fatty Acid Esters Of Glycerol
Ethyl Cellulose
Ferrous Ammonium Phosphate
Isopropyl Alcohol
L-Theanine
Meso-Zeaxanthin
Methyl Salicylate
Methylparaben
Potassium Nitrate
Propylparaben
Spice Oleoresins
Sucromalt
Trehalose
Yeast Extract

COMMENTARY— *FCC* Seventh Edition, Third Supplement

Monograph/Sections: ARA from Fungal (*Mortierella alpina*) Oil/Multiple Sections

Expert Committee: Food Ingredients
No. of Commenters: 3
Comment Summary #1: The commenter requested that the fatty acid dihomo-gamma-linolenic acid in the *Acceptance criteria* table under *Identification* be changed to homo-gamma-linolenic acid to reflect accurate stereoisomeric composition of the product.
Response: Comment not incorporated. Data not provided to support the ability of the referenced test method to determine the difference between dihomo-gamma-linolenic acid and homo-gamma-linolenic acid.

Comment Summary #2: The commenter requested that many of the proposed specifications in the *Acceptance criteria* table under *Identification* be changed to reflect data submitted from additional lots of the ingredient. Changes requested are as follows:

Fatty Acid	Shorthand Notation	Lower Limit (Area%) in Forum	Lower Limit (Area%) Proposed by Comments	Upper Limit (Area%) in Forum	Upper Limit (Area%) Proposed by Comments
Myristic Acid	**14:0**	0	0.1	2.0	0.5
Palmitic Acid	**16:0**	4.2	4.3	8.3	8.1
Palmitoleic Acid	**16:1 n-0**	0	No Change Requested	0.2	0.4
Stearic Acid	**18:0**	3.4	4.2	8.0	7.6
Oleic Acid	**18:1 n-9**	2.9	3.4	7.0	9.5
Linoleic Acid	**18:2 n-6**	5.6	3.8	10.1	15.2
Gamma-Linolenic Acid	**18:3 n-6**	1.8	1.7	3.0	2.7
Arachidic Acid	**20:0**	0.6	No Change Requested	0.9	1.0
Homo-Gamma-Linolenic Acid	**20:3 n-6**	3.5	3.0	5.0	No Change Requested
Arachidonic Acid	**20:4 n-6**	40.0	No change Requested	48.5	No Change Requested
Behenic Acid	**22:0**	2.8	2.5	4.0	4.1
Lignoceric Acid	**24:0**	9.0	7.8	11.2	12.6

Response: Comment incorporated.
Comment Summary #3: The commenter requested that the *Analysis* in the *Assay* be clarified to reflect that the calculation gives the ARA percentage as a percentage of total fatty acids, and not as a percentage of fat.
Response: Comment incorporated.
Comment Summary #4: The commenter requested that many of the proposed specifications in the *Acceptance criteria* table under *Identification* be changed to reflect product specifications for ingredients that exist in the marketplace, based on regulatory approval documents and the commenter's own analyses. Changes requested are as follows:

Fatty Acid	Shorthand Notation	Lower Limit (Area%) in Forum	Lower Limit (Area%) Proposed by Comments	Upper Limit (Area%) in Forum	Upper Limit (Area%) Proposed by Comments
Myristic Acid	**14:0**	0	No Change Requested	2.0	2
Palmitic Acid	**16:0**	4.2	3	8.3	15
Palmitoleic Acid	**16:1 n-0**	0	No Change Requested	0.2	2
Stearic Acid	**18:0**	3.4	5	8.0	20
Oleic Acid	**18:1 n-9**	2.9	5	7.0	38
Linoleic Acid	**18:2 n-6**	5.6	4	10.1	15
Gamma-Linolenic Acid	**18:3 n-6**	1.8	1	3.0	5

Fatty Acid	Shorthand Notation	Lower Limit (Area%) in Forum	Lower Limit (Area%) Proposed by Comments	Upper Limit (Area%) in Forum	Upper Limit (Area%) Proposed by Comments
Arachidic Acid	**20:0**	0.6	0	0.9	1
Homo-Gamma-Linolenic Acid	**20:3 n-6**	3.5	1	5.0	5
Arachidonic Acid	**20:4 n-6**	40.0	38	48.5	48
Behenic Acid	**22:0**	2.8	0	4.0	4
Lignoceric Acid	**24:0**	9.0	9	11.2	11

Response: Comment not incorporated. The existing proposed limits are based on a large amount of actual product data. The commenter did submit a limited amount of supporting data. However, it is not clear that the commenter's data was obtained using the same methodology specified in the proposed monograph. The FIEC does not support replacing these limits, which are based on data submitted, with limits based on regulatory approvals (where the actual data is not available). Data from further analyses, if provided, may be used to support a future proposal for revisions in an upcoming *FCC Forum*.

Comment Summary #5: The commenter requested that the *Acceptance criteria* in the *Peroxide Value* test be changed from "NMT 2.0 mEq/kg" to "less than 5 mEq/kg" to reflect product specifications for ingredients that exist in the marketplace. This request is based on regulatory approval documents submitted with comments.

Response: Comment not incorporated. The existing proposed limit is based on actual product data. The FIEC does not support replacing this limit, which is based on data submitted, with a limit based on regulatory approvals. Data from further analyses, if provided, may be used to support a future proposal for a revision in an upcoming *FCC Forum*.

Comment Summary #6: The commenter requested that the *Acceptance criteria* in the *Unsaponifiable Matter* test be changed from "NMT 3.0%" to "less than 3.5%" to reflect product specifications for ingredients that exist in the marketplace. This request is based on regulatory approval documents submitted with comments.

Response: Comment not incorporated. The existing proposed limit is based on actual product data. The FIEC does not support replacing this limit, which is based on data submitted, with a limit based on regulatory approvals. Data from further analyses, if provided, may be used to support a future proposal for revision in an upcoming *FCC Forum*.

Comment Summary #7: The commenter requested that the *Acceptance criteria* in the *Lovibond Color* test be changed from "Yellow: NMT 50; Red: NMT 5" to "Yellow: less than 70; Red: less than 6." No rationale or supporting data was supplied with this comment.

Response: Comment not incorporated. The FIEC did not receive sufficient data or rationale to incorporate this change. In response to a separate comment, however, the applicable section has been deleted (see Comment Summary #12).

Comment Summary #8: The commenter requested that the term “ARA Rich Single-Cell Oil” be added to the list of synonyms in the chemical information section of the monograph on the basis that this is a name for the ingredient that is currently used in the marketplace.
Response: Comment incorporated.
Comment Summary #9: The commenter requested that the wording of the *Description* section be changed to indicate that the extraction of the ingredient from *Mortierella alpina* fermentation usually is done using solvents. The commenter believes that the current wording, which does not include the word “usually,” limits innovation and development of alternative manufacturing technologies.
Response: Comment incorporated.
Comment Summary #10: The commenter requested that the wording of the *Description* section be changed from “The oil may be winterized, bleached, and deodorized…” to “The oil may be refined, winterized, bleached, and deodorized…” No rationale or supporting data was supplied with this comment.
Response: Comment not incorporated. The FIEC did not accept this change because allowable operations of winterizing, bleaching, and deodorizing, all of which may be considered part of the “refining” process, are already included in the *Description*. “Refining” can further mean such processes as hydrogenation, which could significantly change the composition of the oil and create an ingredient that could no longer be described by the standard proposed.
Comment Summary #11: The commenter requested that the minimum specification for ARA (arachidonic acid) in the *Acceptance criteria* table under *Identification* as well as in the *Acceptance criteria* for the *Assay* be changed from a minimum of 40.0% to a minimum of 36.0% to ensure consistency with global regulatory approvals for this ingredient.
Response: Comment not incorporated. The FIEC did not agree that a minimum content of 36% was supported by regulatory approvals. Furthermore, the limit was set based on actual product data received and no data was supplied by the commenter to document the need for a minimum ARA content of 36%. The FIEC did make a separate change to this specification: see Expert Committee Initiated Change #1.
Comment Summary #12: The commenter requested that the test and specification for *Lovibond Color* be removed from the proposed monograph on the basis that the color of the ingredient is unrelated to regulatory requirements or safety issues Furthermore, the commenter believes that a color requirement is unnecessarily prescriptive, potentially restrictive, and gives a commercial advantage to one manufacturer of the ingredient.
Response: Comment incorporated.
Comment Summary #13: The commenter requested that the *Acceptance criteria* table under *Identification* be entirely removed on the basis that the fatty acid profile has no relevance to the safety of the product, nor to its functional properties. The commenter stated that the select group of fatty acids present in the table does not characterize the ingredient and it is their belief that specifying the fatty acid profile is unnecessarily prescriptive and provides a commercial

advantage to one manufacturer of the ingredient. Furthermore, global regulatory approvals for this ingredient specify only ARA content and it is the commenter's belief that the monograph should also only specify ARA content.
Response: Comment not incorporated. The FIEC believes that the fatty acid composition requirements in the *Identification* section are essential to proper identification of this ingredient, which is essential to the monograph. No data was supplied to support the claim that these specifications provide a commercial advantage for one manufacturer and no alternative *Identification* technique was identified by the commenter.
Expert Committee Initiated Change #1: The FIEC changed the minimum specification for ARA in the *Identification* and *Assay Acceptance criteria* from 40.0% to 38.0% to remain consistent with minimum ARA content required (and supported by data) in regulatory approval documents.

Monograph/Sections: Monk Fruit Extract/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 3
Comment Summary #1: The commenter requested that the test and specification for *Cadmium* be removed from the proposed monograph on the basis that the ingredient is a high potency sweetener and that other, similar, high potency sweeteners in the *FCC* do not have *Cadmium* limit requirements.
Response: Comment not incorporated. The FIEC did not agree with removing the *Cadmium* specification on the basis provided by the commenter. This ingredient is extracted from plant material known to be grown primarily in areas where contamination of soil with metals can be problematic.
Comment Summary #2: The commenter requested that the *Acceptance criteria* in the test for *Arsenic* be changed from "NMT 0.5 mg/kg" to "NMT 2 mg/kg" on the basis that the ingredient is a high potency sweetener and that other, similar, high potency sweeteners in the *FCC* either have no *Arsenic* limit or have an *Arsenic* limit of NMT 1 mg/kg (Rebaudioside A). The commenter also believes that the proposed limit of NMT 0.5 mg/kg requires testing by ICP-MS, which is uncommon in analytical labs. Changing the limit to NMT 2 mg/kg would allow the use of ICP-OES, which is more common instrumentation.
Response: Comment not incorporated. The FIEC did not agree with changing the *Arsenic* specification on the basis provided by the commenter. This ingredient is extracted from plant material known to be primarily grown in areas where contamination of soil with metals can be problematic. The limit in the proposed monograph was set based on data submitted. The FIEC also notes that they do not believe that ICP-MS is strictly required and that atomic absorption and other techniques can reach the required limit of detection.
Comment Summary #3: The commenter requested that the test and specification for *Thin-Layer Chromatography* under *Identification* be replaced with a test for *Infrared Absorption* with comparison to a Mogroside V (98%) reference material. Analytical spectra were submitted to support the request. The commenter indicates that Fourier-transform infrared absorbance (FTIR) instruments are very common in analytical laboratories and that they allow for

more timely and cost-effective analysis than thin-layer chromatography. Industry has used FTIR successfully for identity testing for many years.
Response: Comment not incorporated. The FIEC agrees that FTIR is a common and powerful analytical technique for identification, however, it would be inappropriate to use a nearly pure Mogroside V reference material to identify an article that has a Mogroside V content as low as 30% (according to the limit allowed by the *Assay*). Thin-layer chromatography is an appropriate identification technique for botanical extracts and gives a greater quantity of information about the sample than FTIR would (in the case of this ingredient).
Comment Summary #4: The commenter requested that the *Acceptance criteria* in the *Assay* for *Mogroside V Content* be changed from “NLT 30.0%” to “NLT 25.0%” on the basis that the ingredient is currently available with Mogroside V content varying from 25% to 55%. The commenter believes that limiting the minimum specification for Mogroside V to 30%, without a compelling safety issue, confers an unfair trade disadvantage to companies marketing the product at 25% Mogroside V.
Response: Comment not incorporated. The FIEC did not receive information or data relating to products with Mogroside V content as low as 25% and could not confirm the overall composition of these ingredients as compared to the article that was the basis of the proposed monograph. While it may be possible that an alternate method of manufacture may yield a product with lower Mogroside V content than the proposed specification, it was not clear to the FIEC that such products are approved for use in foods and the FIEC was not provided with manufacturing details or regulatory information supporting the use of such products.
Comment Summary #5: The commenter requested that the title of the monograph be changed from “Monk Fruit Extract” to “Luo Han Guo Extract” and that the term “Monk Fruit Extract” be added to the list of synonyms in the Chemical Information section of the monograph. The commenter submitted information from the USDA’s Germplasm Resource Information Network database and from *Herbs of Commerce* (1992) that lists this ingredient with a common name of Luo Han Guo and not Monk Fruit. The commenter further notes that this ingredient is also used in dietary supplements and that USP’s own procedures and regulatory requirements would not enable USP to call a monograph for this ingredient published in *USP-NF* “Monk Fruit Extract”, rather the name from *Herbs of Commerce* (1992) would be used. The commenter further believes that titling the monograph “Monk Fruit Extract” is confusing to users who know the ingredient as Luo Han Guo and confers an unfair trade disadvantage to companies marketing the product as Luo Han Guo.
Response: Comment not incorporated. The FIEC acknowledges that a dietary supplements monograph may be required to use a different title. However, information submitted when proposing the monograph indicated that the current title is non-proprietary and is used by multiple manufacturers in the food industry. The FIEC also noted that the title proposed by the commenter is problematic because it is an English spelling of a Chinese term and, as such, there are multiple ways that the term may be spelled using the English alphabet, which

may further confuse users. Finally, users are not required to label their ingredient according to the *FCC* title (according to *FCC* policy) and the term “Luo Han Guo Extract” is in the list of synonyms for this ingredient in the Chemical Information section of the monograph.

Monograph/Sections: Ethyl Lauroyl Arginate/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 1
Comment Summary #1: The commenter requested that the concentration of sulfuric acid used in the *Mobile phase* be clarified to be on a volume/volume basis.
Response: Comment incorporated
Comment Summary #2: The commenter requested for the *Related Compounds* test procedures that the injection volume be reduced from 50 µL to 10 µL to improve peak shapes.
Response: Comment not incorporated. Data not provided on the impact of a reduced injection volume on the limit of quantitation for the test.
Expert Committee Initiated Change #1: The FIEC changed *Sample solution*, *Standard solution,* and *Diluent* instructions in the *Assay* and *Related Compounds* procedures to provide more detailed information how to appropriately dissolve the compounds used in these solutions.
Expert Committee Initiated Change #2: For the *Related Compounds* procedure, the FIEC clarified the instructions for preparing and use of the *Standard solution* by adding instructions for preparation of a separate *Resolution solution* and use this solution in the *System suitability* procedure.

Monograph/Sections: Calcium Cyclamate/Impurities (Lead)
Expert Committee: Food Ingredients
No. of Commenters: 1
Comment Summary #1: Commenter requested to use the general test for heavy metals used for the Sodium Cyclamate monograph of the British and European Pharmacopeias.
Response: Comment not incorporated. The proposed analysis is not quantitative nor does it differentiate between specific heavy metals and thus could not replace the analysis for lead. Moreover, no data were provided related to tests or limits for heavy metals specific to the methods of manufacture of these materials.

Monograph/Sections: Sodium Cyclamate/Impurities (Lead)
Expert Committee: Food Ingredients
No. of Commenters: 1
Comment Summary #1: Commenter was requested to use the general test for heavy metals used for the Sodium Cyclamate monograph of the British and European Pharmacopeias.
Response: Comment not incorporated. The proposed analysis is not quantitative nor differentiates between specific heavy metals and thus could not

replace the analysis for lead. Moreover, no data were provided related to tests or limits for heavy metals specific to the methods of manufacture of these materials.

Monograph/Sections: Sodium Chloride/various sections
Expert Committee: Food Ingredients
No. of Commenters: 1
Comment Summary #1: The commenter requested not to make the changes in the proposal *Description*, and not to change the maximum use level of 13 mg/kg for the use of sodium ferrocyanide, since this change was not petitioned to the US FDA or by a US producer and thus cannot be approved nor announced in the US Federal Register.
Response: Comment not incorporated. Given the usage of these additives in global markets, this request is consistent with the global nature of the *FCC*. While calcium and potassium ferrocyanide are not currently regulated for this use in the US, companies always have the option of performing their own self-GRAS determination if they choose to use these ingredients in the US. Additionally, as indicated on pp. 2-3 of the General Provisions and Requirements section of *FCC 7*, information provided in the *Description* section of the monograph are not requirements, but are provided as information only.
Comment Summary #2: The commenter requested a change in the *Specific Tests*, *Ferrocyanides* section to clarify that decahydrate ferrocyanide usually loses hydration water over time, and thus must be dried down to its stable anhydrous form if it is to be used to make the *Control solution*.
Response: Comment incorporated.