COMMENTARY—*Food Chemicals Codex* (*FCC)* Seventh Edition
March 9, 2010

Revision proposals published in *Food Chemicals Codex (FCC) Forum* often elicit public comments that are forwarded to the Food Ingredients Expert Committee (FIEC) for review and response. In accordance with the Rules and Procedures of the 2005-2010 Council of Experts, revision proposals can advance to publication with minor modifications, as needed, without requiring further public review. In such cases a summary of comments are published on the USP website. For those proposals that require further revision and republication in *FCC Forum*, a summary of the comments and the FIEC's responses will be included in the briefing that accompanies each article.

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 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* section prevails.

For further information, contact:
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No comments received for the following proposals:

General Tests and Assays
Appendix III -- Chemical Tests and Determinations
Appendix VII -- Fats and Related Substances

Monographs
Acesulfame Potassium
Adipic Acid
Bentonite
Benzaldehyde
Butyl Acetate
Choline Bitartrate
Choline Chloride
Cyclohexane
Erythritol
Ethyl Formate
Folic Acid
High Oleic Soybean Oil (Unhydrogenated)
Isobutyl Acetate
Isomaltulose
Isopropyl Acetate
L-Methionine

No comments received for the following proposals:

Monographs

L-Phenylalanine
L-Proline
L-Serine
L-Threonine
L-Tryptophan
L-Tyrosine
L-Valine
Magnesium Lactate
Magnesium Phosphate, Dibasic, Trihydrate
Neotame
Nisin Preparation
Polysorbate 40
Polyvinyl Acetate
Propyl Acetate
Pullulan
Sodium Stearyl Fumarate
Sorbitan Monolaurate
Sorbitan Monopalmitate
Sorbitan Tristearate
Sucralose
Sugar Beet Fiber
Trehalos

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MONOGRAPHS

Monograph/Section(s): Alitame/Description
Expert Committee: Food Ingredients
No. of Commenters: 0
Expert Committee Initiated Change: The FIEC removed the sentence under *Description* comparing the sweetness of Alitame to that of sucrose because this ratio is highly variable and may mislead users.

Monograph/Section(s): Lutein/Multiple
Expert Committee: Food Ingredients
No. of Commenters: 2
Comment Summary #1: The commenter suggested that the *Acceptance criteria* for zeaxanthin under *Organic Impurities, Zeaxanthin and Other Related Compounds* be changed from “NMT 8.5%” to “NMT 12.0%” to more accurately reflect the percentage of zeaxanthin that can be obtained in extracted lutein products with specific extraction techniques. To support this change, the commenter also suggested that the peak area of zeaxanthin in the *Analysis* under the same test be changed from “NMT 9.0%” to “NMT 15.0%”.
Response: Comment not incorporated. Data was not submitted to support that lutein products in commerce have a zeaxanthin content as high as 12.0%.

Comment Summary #2: The U.S. Food and Drug Administration (FDA) commented on the *Function* section under *Description*, which indicates that this ingredient is used as a color. The FDA noted that Lutein is not permitted for use as a color additive in the United States and that, to be used as such, premarket review and approval of the ingredient as a color additive may be required. The full text of the comment can be seen at http://www.usp.org/pdf/EN/fcc/fdaFCCForumJune2009.pdf

Response: Comment not incorporated. The comment implied a proposed change to the *Function* section under *Description* to remove the "color" function, but the FIEC did not wish to incorporate this change because the *FCC* is intended to be an international compendium of food ingredients and, as such, will contain items that are permitted for use in foods in other countries. Lutein is used as a color in other countries; it is the sole responsibility of the ingredient user to determine the appropriate regulatory status of any ingredient they use.
Expert Committee Initiated Change: The FIEC changed the *Acceptance criteria* for zeaxanthin under *Organic Impurities, Zeaxanthin and Other Related Compounds* from "NMT 8.5%" to "NMT 9.0%" to reflect a limit consistent with that appearing in the Lutein monograph prepared at the 63rd session of the FAO/WHO Joint Expert Committee on Food Additives (2004). The FIEC also removed the requirement under "Analysis" that the peak area of zeaxanthin be "NMT 9.0" as unnecessary text that is implied by the limit.

Monograph/Sections: Sodium Iron EDTA / Assay
Expert Committee: Food Ingredients
No. of Commenters: 0
Expert Committee Initiated Change #1: The FIEC changed the *Acceptance criteria* for the assay of *EDTA* from "65.5% - 70.5%" to "67.0% - 72.0%" so that the range represents the theoretical value +/- 2.5%. Data was received that supports this limit.

Monograph/Section(s): Tagetes Extract/Description
Expert Committee: Food Ingredients
No. of Commenters: 1
Comment Summary: The FDA commented on the *Function* section under *Description*, which indicates that this ingredient is used as a color. The FDA noted that Tagetes Extract is only permitted for use in chicken feed in the United States. This item is not authorized for use as a color additive in human food in the U.S. They further noted that there are a number of specifications for this ingredient, when used in chicken feed, in the Code of Federal Regulations (21 CFR 73.295) that are not consistent with the proposed draft monograph. The full text of the comment can be seen at http://www.usp.org/pdf/EN/fcc/fdaFCCForumJune2009.pdf
Response: Comment not incorporated. The comment implied a proposed change to the *Function* section under *Description* to remove the "color" function, but the FIEC did not wish to incorporate this change because the *FCC* is intended to be an international compendium of food ingredients and, as such, will contain items that are permitted for use in foods in other countries. Tagetes Extract is used as a color in other countries; it is the sole responsibility of the ingredient user to determine the appropriate regulatory status of any ingredient they use. Further, the proposed monograph is not intended to represent the ingredient sold in the U.S. for use in chicken feed, so the FIEC sees no reason to harmonize the monograph with the Code of Federal Regulations section pertaining to the use of Tagetes Extract as a color additive for use in chicken feed.

Monograph/Section(s): Appendix IIC / Water-Insoluble Matter
Expert Committee: Food Ingredients
No. of Commenters: 1
Comment Summary: The commenter suggested changing the instructions under *Sample Preparation* to remove the "5 g" and replace it with "the amount of sample specified in the individual monograph" so that the test can accommodate many types of monographs.
Response: Comment incorporated with changes. The FIEC added the parenthetical "(if a different amount of sample is specified in the individual monograph, use that amount)" after the "5 g" sample size under *Sample Preparation* so that the test can be used for different types of monographs.