Commentary
Food Chemicals Codex (FCC), 1st Supplement to the Thirteenth Edition

September 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, along with a summary of any FIEC-initiated changes, 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, and the basis for any FIEC-initiated changes. 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) Forum:

- *2'-Fucosyllactose*
- *Fructooligosaccharides, Short Chain*
- *Isopropyl Alcohol*
- *Mycoprotein*
- *Xylooligosaccharides*

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

- *Alginate-Konjac-Xanthan Polysaccharide Complex*
- *Alitame*
- *β-Apo-8'-Carotenal*
- *Appendix VIII—Oleoresins*
- *Appendix XIII—Adulterants and Contaminants in Food Ingredients*
- *Appendix XVI—Protein-Based Ingredients*
- *Caramel*
- *Choline Bitartrate*
- *Choline Chloride*
- *General Provisions and Requirements Applying to Specifications, Tests, and Assays of the Food Chemicals Codex*
- *Jagua (Genipin-Glycine) Blue*
- *Plant Stanol Esters*
- *Sodium DL-Malate*

Monograph/Section(s): 2'-Fucosyllactose/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 3

Comment Summary #1: A commenter requested three chemical names be added to the synonym list in the *Chemical Information* section. The chemical names proposed by the commenter were D-Glucose, *O*-6-deoxy-α-L- galactopyranosyl-(1→2)-*O*-β-D-galactopyranosyl-(1→4) -; *O*-6-Deoxy-α-L-galactopyranosyl-(1→2)-*O*-β-D-galactopyranosyl-(1→4)-D-glucose; and 4-*O*-(2-*O*-(6-*O*-Deoxy-α-L-galactopyranosyl)-β-D-galactopyranosyl)-D-glucose.
Response: Comment incorporated. The three chemical names identified in the comment are appropriate synonyms and were added to the synonym list.
Comment Summary #2: A commenter requested three chemical names be removed from the synonym list in the *Chemical Information* section on the basis that the names describing "glucopyranose" here are not correct in current chemical nomenclature.
Response: Comment incorporated. The following synonyms were removed on the basis that they are not consistent with current chemical nomenclature from the synonym list: 4-*O*-[2-*O*-(6-Deoxy-α-L-galactopyranosyl)-β-D-galactopyranosyl]- D-glucopyranose;

4-*O*-[2-*O*-(α-D-Fucosyl)-β-D-galactopyranosyl]- D-glucopyranose; α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)- D-glucopyranose.
Comment Summary #3: A commenter requested "2'-FL" be removed from the synonym list in the *Chemical Information* section as it is not a scientific synonym.
Response: Comment not incorporated. 2'-FL is a commonly used acronym in literature and in the food industry; as such it is appropriate for the synonym list.
Comment Summary #4: A commentor requested the removal of **"**Fuc-α-(1→2)-Gal-β-(1→4)-Glc" from the synonym list in the *Chemical Information* section on the basis that it is a shorthand convention for the oligosaccharide sequence rather than a chemical name.
Response: Comment incorporated. "Fuc-α-(1→2)-Gal-β-(1→4)-Glc" was removed from the synonym list.
Comment Summary #5: The commenter indicated that "2'-fucosyl-D-lactulose," which is required for *System suitability solution 1* in the *Assay*, does not seem to be commercially available; given this the commenter requested that users be given more information on how to obtain 2'-fucosyl-D-lactulose.
Response: Comment incorporated. The following instructions for preparing 2'-fucosyl-D-lactulose were added to *System suitability solution 1* in the *Assay*: "Weigh 1 mg of D-lactose into a 5-mL volumetric flask. Add approx. 4 mL of *Standard solution 2* as well as 5 µL of triethylamine. Dilute to volume with *Standard solution 2*. Close the flask tightly also using a safety clip or similar. Heat the flask for 30 min at 70° in a warming cabinet. After 30 min, cool the flask down to room temperature."
Comment Summary #6: A commenter requested the addition of the retention time for 2'-fucosyl-D-lactulose to the *System suitability requirements (Resolution)* to provide clarity.
Response: Comment incorporated. The relative retention time of 2'-fucosyl-D-lactulose (necessary for the *System suitability requirement* in the *Assay*) was added to *Table 1* and D-lactose, *System suitability solution 1* to provide clarity. Additionally, the following Note to describe the purpose of the procedure to produce 2'-fucoysl-D-lactulose was also added for clarity: "[NOTE—This procedure gives rise to detectable amounts of 2'-fucosyl-D-lactulose for peak identification.]"
Comment Summary #7: A comment was received requesting the standard curve generated and included in the *Analysis* for the *Related Compounds* test not be forced through the origin on the basis that forcing the standard curve through the origin may change the slope of the curve and lead to incorrect calculation of the analytes of interest.
Response: Comment incorporated for the reason provided by the commenter.
Comment Summary #8: A comment was received indicating an error within the *Related Compound* analysis. The commenter states that the solution described as *Calibration standard solution 3* in *Related Compounds* should instead be *Standard solution 3* as defined in the *Assay*.
Response: Comment incorporated. To correct the error, c*alibration standard solution 3* was changed to *Standard solution 3* in the *Related Compounds* test.
Comment Summary #9: A comment was received requesting the addition of "Sum of other carbohydrates NMT 8.0%, calculated as 2'-fucosyllactose on the anhydrous basis" to the *Acceptance criteria* in *Related compounds* to ensure the mass balance is fully

accounted for and allows only carbohydrates.
Response: Comment not incorporated. The requested additional parameter is already implied within the first specification in *Table 2* which indicates that the sum of 2'-fucosyllactose (as determined in the *Assay*), l-fucose, d-lactose, and 3,2'-difucosyl-d-lactose is "NLT 92%, calculated as 2'-fucosyllactose on the anhydrous basis".

Monograph/Section(s): Fructooligosaccharides, Short Chain/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 2

Comment Summary #1: A commenter requested the addition of a procedure for drying the sample used in the *Sample stock solutions* in the *Identification* and *Assay*. The commenter did not submit proposed instructions or supporting data.
Response: Comment not incorporated. Proposed instructions for drying the material and data supporting the technique were not received. A revision to include an appropriate drying procedure may be considered for inclusion in a future *FCC Forum* if a proposed drying technique and supporting data are received.
Comment Summary #2: A commenter requested relative retention times of the components be added to the *Assay*.
Response: Comment not incorporated. The relative retention times were not provided in the comment, therefore additional data is required to provide relative retention times in the *Assay*. A revision to include relative retention times will be considered for inclusion in a future *FCC Forum* if relevant data is received.

Monograph/Section(s): Isopropyl Alcohol/Organic Impurities
Expert Committee: Food Ingredients
No. of Commenters: 1

Comment Summary #1: A commenter requested the removal of methanol from the *Acceptance criteria* in the *Volatile Impurities* test. The commenter indicated manufacturers were substituting methanol for isopropyl alcohol or ethanol in alcohol-based hand sanitizers rather than using adulterated ethanol; in the commenter's opinion, the proposed revisions do not address the FDA's ultimate concern, which was contamination of the alcohol used to manufacture hand sanitizers.
Response: Comment not incorporated. Adulteration of Isopropyl Alcohol with methanol, due to substitution or contamination, is concerning due to the toxic effects of methanol. Methanol in hand sanitizer products continues to be identified by the US-FDA (FDA updates on hand sanitizers consumers should not use | FDA), indicating that the products remains vulnerable to adulteration. An appropriate test and specification for quantitation of methanol are needed in the *Isopropyl Alcohol* monograph to protect public health.

Monograph/Section(s): Mycoprotein/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 2

Comment Summary #1: A commenter requested the addition of the genus and species of the microbial source of the Mycoprotein to the title of the monograph to clarify the specific subject of the monograph.
Response: Comment incorporated. The title of the monograph was revised from "*Mycoprotein*" to *"Mycoprotein from* Fusarium venenatum."
Comment Summary #2: A commenter requested that the *Description* in the monograph identify the type of fermentation specific to this mycoprotein.
Response: Comment not incorporated. Currently, it is not necessary to include specific details regarding the fermentation process in the monograph. If the fermentation process becomes relevant to the quality of the final product with the addition of other "mycoprotein" monograph submissions, a revision to add specific fermentation information will be proposed in a future *FCC Forum*.
Comment Summary #3: A comment was received regarding the final concentration of the *Internal standard solution* in the *Sample solution* and the *Calibration standard solution* in *Identification A* (*Amino Acid Profile*). The concentration of the *Internal standard solution* in the *Sample solution* is 200 nmol/ml, while the concentration in the *Calibration standard solution* is 20 nmol/ml. Since the method is based on ISO 13903-2005, the concentration of the internal standard in both the *Standard solution* and the *Calibration standard solution* should be 200 nmol/ml.
Response: Comment incorporated. The text was revised from "Add 0.50 mL of the *Internal standard solution*" to "Add 5.0 mL of the *Internal standard solution*" in the *Calibration standard solution* for the *Amino Acid Profile* test in *Identification A* for consistency with ISO 13903-2005.

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

Comment Summary #1: A commenter requested the *Tailing factor* for xylose in the *Assay* be revised from "NMT 1.05" to "NMT 2.0" as NMT 1.05 is highly restrictive and not typical for ingredient monographs.
Response: Comment incorporated. The tailing factor for xylose in the *Assay* has been revised from "NMT 1.05" to "NMT 2.0", to represent typical chromatographic expectations and data acquired by USP.