



Commentary
Food Chemicals Codex (FCC), 2nd Supplement to the Fourteenth Edition

March 3, 2025

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. 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 or general test or assay, alone and independent of the *Commentary*, prevails.

For further information, contact:

USP Executive Secretariat
U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790 USA
execsec@usp.org

Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCC Forum):

General Tests and Assays

[Appendix XX - Honey Guidance, Methods, and Applicable Resources](#)

Monographs

[Cochineal Extract](#)

[Fructooligosaccharides from Inulin](#)

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

General Tests and Assays

Appendix XIX--Olive Oil Guidance, Methods, and Applicable Resources

Appendix XVI -- Protein-Based Ingredients

Monographs

Fructooligosaccharides, Short Chain

Honey

Lactoferrin, from Bovine (*Bos taurus*) Milk

Lecithin

Mung Bean Protein

Pullulan

Rice Protein

Vitamin B12

General Tests and Assay

General Tests and Assay/Section(s):	Appendix XX - Honey Guidance, Methods, and Applicable Resources
Expert Committee:	Food Ingredients
No. of Commenters:	0

Expert Committee initiated change #1: A comment related to C4 sugars in honey and positive EA/LC IRMS results was added to add additional clarity and information beneficial for stakeholders.

Expert Committee initiated change #2: The titles "Other contributing factors: supply chain" and "Other contributing factors: audit strategy" were changed to "Supply chain" and "Audit strategy" for consistency and conciseness

Expert Committee initiated change #3: The wording "Honey is much more expensive to produce than other sugar syrups" was changed to "Honey is much more expensive to produce than most sugar syrups, particularly those from plants such as corn, rice, sugarcane, and sugar beets." Additionally, "other" was deleted from the sentence: "Therefore, there is a strong economic advantage for replacing honey with other sugar syrups and a long documented history of honey fraud." These changes clarify that honey is not a type of sugar syrup and improve overall clarity.

Expert Committee initiated change #4: The section numbering in the "Honey Fraud Mitigation Guidance" was revised to improve the logical flow of information. *Section 5.2.3* was renumbered as 5.3, with subsequent sections adjusted accordingly.

This resulted in the following updated structure:

B. HONEY FRAUD MITIGATION GUIDANCE

1. Terminology
2. Scope
3. Background
4. Introduction to the Guidance
5. Step 1: Contributing Factors Assessment
 - 5.1. Supply chain
 - 5.2. Audit strategy
 - 5.2.1 Audits of beekeepers
 - 5.2.2 Audits of processing facilities
 - 5.3 Supplier relationship
 - 5.4 History of supplier regulatory, quality, or safety issues
 - 5.5 Geographical considerations
 - 5.6 Fraud history
 - 5.7 Economic anomalies
 - 5.7.1 Less-than-market and unusually stable pricing
 - 5.7.2 Variable pricing according to destination/quality requirements
 - 5.7.3 Rapid increase of export volumes from a country or region
 - 5.7.4 Correlation between increased imports and exports for a country
 - 5.8 Laboratory-based contributing factors
 - 5.8.1 Susceptibility of quality assurance (QA) methods and specifications
 - 5.8.2 Testing frequency

Expert Committee initiated change #5: The last sentence of *Section 8. Step 4: Mitigation Strategy Development* was revised to "red to orange or to green..." to enhance clarity.

Expert Committee initiated change #6: The following sentence was added to the end of the section *Alternative Specific Methods*: "The use of these markers involves a previous validation with sufficient number of honey varietals to determine if the compound is not naturally present in any type of honey, or indeed present but in low concentrations in some special honey types." to provide important context and information regarding the use of markers.

Monograph

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

Comment Summary #1: The commenter requested a rationale for the HPLC test because it is different from the spectrophotometric method from the tentative JECFA monograph.

Response: Comment not incorporated. The HPLC test is developed and validated by the USP internal laboratory with commercial samples. It is more specific and modernized than the spectrophotometric method.

Monograph/Section(s): Fructooligosaccharides from Inulin/Multiple Sections
Expert Committee: Food Ingredients
No. of Commenters: 1

Description

Comment Summary #1: The commenter requested changing the color description from "clear to slightly yellow" to "clear to gold".

Response: Comment partially incorporated. Based on the commenter's supplied information, the description of the color and texture can be changed to "a colorless to yellow, viscous syrup".

Identification

Comment Summary #2: The commenter requested adding the statement "The following or similar description methods and calculations can be used to identify oligofructose." to the *Identification* test to allow for alternative methods and adding "or Shodex KS-801 or KS-802" to footnote 1 for additional columns.

Response: Comment not incorporated. The use of alternative procedures is discussed in the *General Provisions and Requirements* section *Alternative Analytical Procedures*.

Although the tests and assays described constitute procedures upon which the specifications of the *FCC* depend, analysts are not prevented from applying alternative procedures if supporting data shows that the procedures used will produce results of equal or greater accuracy. In the event of doubt or disagreement concerning a substance purported to comply with the specifications of the *FCC*, only the methods described herein are applicable and authoritative. This allows flexibility for stakeholders to use alternative methods. The Expert Committee will consider future revisions to the monograph upon the receipt of supporting data.

Assay

Comment Summary #3: The commenter requested to change the *Acceptance criteria* for the Assay from NLT 85% to NLT 83%, calculated on the dried basis.

Response: Comment incorporated. The Assay has been changed to NLT 83% based on the information received.

Loss on Drying

Comment Summary #4: The commenter suggested adding references to alternative methods to determine Brix in the *Loss on Drying* test.

Response: Comment not incorporated. *Loss on Drying* has been used in other similar monographs such as Isomaltooligosaccharides syrup and powders. Although the loss on drying and the dry matter/total solids methods may have similar purposes, there is a lack of comparison/equivalency data to incorporate this change for this proposal. The Expert Committee will consider future revisions to the monograph upon the receipt of supporting data.