



Commentary

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

September 1, 2021

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 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 Forum (FCCF):

- [Honey](#)

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

- *Appendix XIII – Adulterants and Contaminants in Food Ingredients*
- *Appendix XVI – Protein-Based Ingredients*
- *Annatto Extracts*
- *DHA from Algal (Schizochytrium) Oil*
- *Jagua (Genipin-Glycine) Blue*
- *L-Lysine Acetate*
- *Olive Pomace Oil, Refined*
- *Soy Leghemoglobin*
- *Spice Oleoresins*
- *Tagetes Extract*
- *Terpene Resin, Synthetic*
- *Turmeric Oleoresin*

Monograph/Section(s): Honey (*FCC Identity Standard*) / Multiple Sections

Expert Committee: Food Ingredients

No. of Commenters: 14

Introduction

Comment Summary #1: Five comments were received requesting that the statement “Honey consists primarily of simple sugars, predominantly fructose and glucose, as well as other substances such as organic acids, enzymes, and solid particles derived from nectar collection by bees, including pollen” be replaced with the USDA Commercial Item Description (CID) definition of honey.

Response: Comment not incorporated. This document is intended to be a global, voluntary use document; the inclusion of pollen in the definition of honey, although not included in the USDA CID, is consistent with decisions and authoritative documents in different parts of the world.

Production of Honey

Comment Summary #2: Two comments were received requesting removal of this sentence: “Bees eventually cap the cells when they are full of mature honey.” The commenters indicated common practice in beekeeping is to harvest honey while it is uncapped since capping is not an indication of maturity.

Response: Comment not incorporated. Biologically, bees do eventually cap mature honey, although not all mature honey is capped. The statement is not misleading based on the additional information regarding circumstances when cells may not be capped.

Comment Summary #3: A comment was received requesting the removal of references to moisture in the section *Production of Honey* unless moisture directly reflects the established grading standard.

Response: Comment not incorporated. The text here includes observations and compiled

knowledge, and is intended as background information.

Comment Summary #4: Four comments were received in disagreement with the practices described in the section *Production of Honey* as they may not represent all beekeeping methods used globally. Commenters indicated the section appears to be more directed at temperate beekeeping methods and specific hives. Details and data on production in other regions are lacking, specifically tropical regions where single-chamber hives and tropical beekeeper methods are utilized. The commenters suggested re-wording this section in various ways to be more inclusive or to clarify where these practices are most prevalent.

Response: Comment partially incorporated. Given the diversity of practices globally, the word “frames” was revised to “combs/frames” in the *Production of Honey* section in recognition of the two primary beekeeping practices in various regions.

Comment Summary #5: Two comments requested the removal of the fermentation steps in the section *Production of Honey* as this does not address beekeeping methods used outside of temperate zones and may create a competitive advantage for beekeepers in temperate climates.

Response: Comment not incorporated. Within the *Identification* section there are concessions and differentiations for products from both tropical and temperate climates.

Comment Summary #6: A comment was received regarding the discussion of the types of manipulation bees use to reduce moisture in honey and prevent fermentation. The commenter requested that details be added to describe the bees’ use of their wings to fan the honey in conjunction with natural air to dry the honey.

Response: Comment incorporated. The text was revised as follows (underline added to emphasize the change in the text): “By contrast, passive concentration of nectar occurs through direct evaporation of nectar stored in cells; the concentration inside the beehive is faster for smaller sugar solution volumes that display a larger surface area. Bees fanning their wings at the entrance of the hive also helps reduce the moisture of nectar.”

Comment Summary #7: A comment was received requesting the addition of manual dehumidification as a means of drying honey and the need for human intervention in the dehydration process in humid climates.

Response: Comment not incorporated. Human intervention should not be used at this step in the process, as it would interfere with the process of bees making honey.

Comment Summary #8: A comment was received regarding the statement “Honeys from very humid areas, or produced during humid seasons, may cause exceptions because bees may cap honey containing more than 18% water.” The commenter indicated the wording is overly subjective and it is known that large volumes of honey are produced with a higher moisture content. Honey capped with a moisture content above 18% needs manual moisture reduction with human intervention.

Response: Comment partially incorporated. The section was revised to read as follows (strikeout for deleted text and underline added to emphasize the change in the text): “Honeys from very humid areas or produced during humid seasons may be capped containing more than 18% water.” Honeys from very humid areas or produced during humid seasons may ~~cause exceptions because bees may~~ be capped honey containing more than 18% water.⁵

Composition and Factors

Comment Summary #9: A comment was received requesting that the FDA document entitled *Proper Labeling of Honey and Honey Products: Guidance for Industry* be referenced in *Added ingredients*.

Response: Comment not incorporated. This document is intended to be a global, voluntary use document, and reference to one country’s labeling requirements is inappropriate and may cause confusion.

Comment Summary #10: Two comments were received requesting that clarification and

consistency be added to the following terms in the section *Extraneous matter*: “significantly remove,” “alter the distribution,” and “substantially removes or alters.” The commenters requested that statements be aligned with the definition for filtered honey, which is strained with a mesh size less than 80 microns and must be labeled as filtered honey.

Response: Comment incorporated. The following text was deleted because it was not in alignment with the definition of filtered honey: “The mesh size should be chosen such that the straining does not significantly remove or alter the distribution of the natural pollen. Honey strained with a mesh range which substantially removes or alters the distribution of natural pollen must be labeled as filtered honey.”

Comment Summary #11: Two comments were received requesting the addition of pollen to *Extraneous matter*. The commenters indicated that pollen is not a constituent of honey and should be treated similarly to dust and dirt particles from the beehive and the environment.

Response: Comment not incorporated. This standard considers pollen to be a natural constituent of honey, consistent with various global regulatory bodies.

Comment Summary #12: A comment was received requesting the removal of the labeling requirements from the Identity Standard, especially for “filtered” honey. The commenter stated that this labeling goes beyond regulatory requirements in the United States (referencing the FDA document *Proper Labeling of Honey and Honey Products: Guidance for Industry*) and represents overreach.

Response: Comment not incorporated. The referenced information is being retained because it is useful to purchasers of honey and appropriate for a global standard.

Comment Summary #13: Two comments were received regarding the section *Processing limitations* related to the statement: “Honey must not have any flavor, aroma, or taints derived from processing and/or storage.” Commenters indicated that this statement should be clarified as it pertains to fermentation. With the acceptance criteria for moisture at NMT 20%, fermentation will occur in some cases, which should not render the honey unsalable or spoiled. The commenters requested that the following statement be added: “...except where fermentation may naturally occur due to high moisture content.”

Response: Comment not incorporated. The current wording, which does not allow for odor from fermentation, is consistent with global honey processing practices.

Comment Summary #14: A comment was received regarding *Processing limitations*. The commenter disagreed with the statement “The production of the honey must conserve all constituents...” as it relates back to processing descriptions that lack clarity and stated that it could open the door for challenges. The commenter requested that this statement be either removed or clarified.

Response: Comment not incorporated. The current wording requiring the preservation of all constituents conveys the intended information and does not need clarification, because the section refers to the *Honey Defined by Processing* section, where the six types of honey and their constituents are clearly defined.

Comment Summary #15: A comment was received requesting deletion of the final two sentences in *Processing limitations*. The commenter indicated that these sentences refer to the use of Identification tests to measure quality parameters; the commenter disagreed with the use of these tests for identification of honey.

Response: Comment not incorporated. The current wording of *Processing limitations* conveys the intended information about how honey should not be heated so high as to not meet this identity standard. However, in recognition that one test related to the two sentences referenced by the commenter required clarification, a *Note* was added to the *Acceptance criteria* in *Identification C. HMF Content*. The added *Note* reads as follows: “This is a quality parameter and not an indication of authenticity of honey. This limit takes into account honeys from all regions; most honeys from temperate regions will be not more than 40 mg/kg.”

Comment Summary #16: A comment was received requesting clarification on the term “altered” in the section *Raw honey*. The commenter requested that the language be consistent

with the *Processing limitations* section of the Identity Standard, which states: “Honey must not be heated to such an extent that its essential quality parameters exceed the limits described in this Identity Standard.”

Response: Comment incorporated. The text was revised as follows to provide clarity (underline added to emphasize the change in the text): “Raw honey has not been heated to the extent that its original quality parameters fall outside the criteria as defined in the Identification section.”

Comment Summary #17: A comment was received requesting the removal of all references to labeling requirements from the section *Types of honey* by aligning definitions in this section with the definitions for various honey types in the USDA CID. The commenter indicated that labeling is the jurisdiction of the FDA.

Response: Comment not incorporated. This document is intended to be a global, voluntary-use document; the definitions in the USDA CID are not sufficient for this purpose.

Comment Summary #18: A comment was received requesting revisions to the section *Strained honey*. The commenter requested that specific physiochemical and microscopic characteristics be described. The commenter stated that the terms in the *Strained honey* section are overly generic and unclear without further definition. If more specific requirements cannot be listed, the commenter requested deleting the reference to “physiochemical and microscopic characteristics” in this section.

Response: Comment not incorporated. These terms are consistent with the terminology used in other global standards and accurately convey the characteristics that may be referred to as part of optional supplementary information.

Comment Summary #19: Two comments were received requesting the removal of labeling requirements for *Filtered honey*. The commenters indicated that the proposed labeling requirements would necessitate changes to labels on the majority of honey products packed and sold in the United States, which could confuse consumers. The commenter further indicated that the FDA’s *Proper Labeling of Honey and Honey Products: Guidance for Industry* does not specify identification of styles of honey.

Response: Comment not incorporated. This document is intended to be a global, voluntary-use document; the labeling recommendation is consistent with recommendations and requirements in different parts of the world. FDA’s guidance document, which contains non-binding recommendations, does not specifically address filtered honey.

Comment Summary #20: A comment was received requesting clarification within the sections *Strained honey* and *Filtered honey*. The commenter indicated the following statement suggests that filtered honey cannot declare a floral origin: “Raw and strained honeys may be supplemented by information referring to (i) floral origin.” This would seem to create an inconsistency with the USDA grade standard which does permit filtration and does not limit floral declaration based upon the style.

Response: Comment not incorporated. The current wording conveys the intended information as filtered honey contains no evidence of floral origin, and therefore should not be labeled as such.

Comment Summary #21: A comment was received regarding *Comb honey*. The commenter suggested adding “...in the hive and subsequently removed and typically portioned for sale while preserving the structure of the honeycomb” to the end of the description of *Comb honey*.

Response: Comment incorporated. The description of *Comb honey* was revised to read as follows (underline added to emphasize the change in the text): “Honey in the beeswax comb as stored naturally by the bees in the hive and subsequently removed and typically portioned for sale while preserving the structure of the honeycomb.”

Identification

Comment Summary #22: Three comments were received requesting the removal of A.

Insoluble matter from the proposed standard. The commenters indicated that this test is inappropriate for identification and its use is not required or practiced by the US honey industry.

Response: Comment not incorporated. This test is appropriate for identification as it is used to differentiate between extracted and pressed honey. This document is intended to be a global, voluntary-use document and may not represent the current practices or requirements in specific regions or countries in all cases.

Comment Summary #23: Three comments were received requesting that the values in *Table 1* under *Moisture* be harmonized with the USDA Honey Grades Standard.

Response: Comment not incorporated. The originally proposed values are appropriate given the information and data available.

Comment Summary #24: A comment was received requesting clarification on the use of the refractometer as described in *B. Moisture, Refractometric*. The commenter suggested describing the refractometer as follows (underline added to emphasize the change in the text): "...Abbé, or equivalent, which can be thermostated or temperature compensated to 20°."

Response: Comment incorporated. The description of the refractometer was revised as requested for clarification.

Comment Summary #25: Four comments were received requesting revisions to the *Acceptance criteria* within *C. HMF Content*. One commenter indicated that the US does not view HMF as a quality criterion; the commenter stated that separate limits based on climate will confuse users. The commenters requested setting a single *Acceptance criteria* for HMF in Honey at 80 mg/kg and removal of the second, lower limit. Additional comments indicated that a maximum limit of NMT 40 mg/kg for HMF in "Honeys not of declared origin from tropical climates" represents a significant problem for North American honey processors based on the temperatures that must be applied to process honey in some cases.

Response: Comment incorporated. The *Acceptance criteria* in *C. HMF Content* was revised to provide a single limit of "NMT 80 mg/kg" that should be achievable for all processors.

Comment Summary #26: Six comments were received requesting removal of *C. HMF Content* as the commenters stated that this test is unnecessary.

Response: Comment not incorporated. Limits for *C. HMF* are necessary for the identity of high-quality honey meeting this identity standard. However, the acceptance criteria was revised to provide a single limit of "NMT 80 mg/kg" that should be achievable for all processors, as described the response to Comment Summary #25. Other globally recognized honey standards include HMF values.

Comment Summary #27: A comment was received requesting revisions to *C. HMF Content*. The commenter indicated the maximum HMF levels must pertain to honey at the time of its production and requested this additional information be added to the test.

Response: Comment not incorporated. The current text conveys the intended information, as the maximum HMF content is not intended to pertain to honey at the time of its production. However, the acceptance criteria was revised to provide a single limit of "NMT 80 mg/kg" that should be achievable for all processors, as described the response to Comment Summary #25.

Comment Summary #28: Three comments were received requesting removal of the sections *D. Electrical Conductivity*, *E. Free Acidity*, and *F. Proline Content*. The commenters indicated that these tests are not required by the United States Standards for Grades of Extracted Honey, the U.S. Honey Industry's Standard of Identity, or the USDA CID Honey, or requested by U.S. customers or consumers.

Response: Comment not incorporated. These requirements are intended to differentiate specific types of honey: electrical conductivity is useful to differentiate honeydew from other honey; free acidity can be an indicator of immature honey production and fermentation; and proline content can be used as an indication of adulteration. Additionally, this document is

intended to be a global, voluntary-use document and may not represent the current practices or requirements in specific regions or countries in all cases.

Comment Summary #29: A comment was received regarding a typographical error in the section *F. Diastase Activity*. The commenter indicates that the amount of equilibrated *Substrate solution* added to the flask containing the equilibrated *Sample solution* in the *Analysis* should be 5.0 mL and not 15.0 mL.

Response: Comment incorporated. The instructions were revised to state: "Using a pipette, transfer 5.0 mL of the equilibrated *Substrate solution* to the flask containing the equilibrated *Sample solution*, and mix."

Comment Summary #30: Seven comments were received requesting removal of the section *F. Diastase Activity*. The commenters indicated that diastase is temperature-sensitive and the US honey industry does not test products for diastase. Commenters further stated that honey sold to North American consumers is often treated with heat to de-crystallize products and meet consumer requirements. This treatment may result in honey that cannot meet the required specification for diastase. Honey exposed to higher temperatures during storage or transportation may also fail to meet the limit for diastase activity. This requirement poses a disadvantage to the US honey industry and would result in products being out of specification only a short time after packaging, which is inconsistent with consumer demands.

Response: Comment not incorporated. The section on *F. Diastase Activity* is being retained because diastase levels can be used as indicators of overheating and long aging; additionally, they can be a marker for mature honey production.

Comment Summary #31: A comment was received requesting revisions to the *Acceptance criteria* in *C. HMF Content* and the *Note* related to HMF content after the *Acceptance criteria* in *F. Diastase Activity*. The commenter requested that honeys specifically intended as food ingredients be allowed to exceed the proposed limits for HMF.

Response: Comment not incorporated. The application of limits on HMF for honey is an important aspect of this Identity Standard. The original text has been updated to provide a single limit of "NMT 80 mg/kg" that should be achievable for all processors, as described the response to Comment Summary #25. Honey used as a food ingredient should still meet this identity standard before processing into the food. There are not different criteria for honey consumed as-is and honey incorporated into foods.

Additional Considerations

Comment Summary #32: Two comments were received requesting revisions in the section *Purity and Authenticity*. Since no specific risk assessment information was provided, the commenters requested that mention of a risk assessment either be deleted or that the sentence be revised to state the following (underline added to emphasize the requested change in text): "The risk assessment and appropriateness of the test methods applied as determined to be appropriate between trading partners has to be periodically checked and revised according to new scientific developments."

Response: Comment not incorporated, as the suggested text provides a subjective standard and does not add further clarification. More specific guidance is currently in development and will be proposed in a future *FCC Forum*.

Comment Summary #33: A comment was received regarding the section *Botanical and Geographic Origin* within *Purity and Authenticity*. The commenter requested replacing the term "almost entirely" with "wholly or mainly" in order to maintain consistency within the document. The commenter also indicated that the lack of a specific definition for "wholly or mainly" leaves this parameter up to user interpretation.

Response: Comment incorporated. The term "almost entirely" was revised to "wholly or mainly" to maintain consistent terminology within the Identity Standard.

Comment Summary #34: Two comments were received requesting revisions to *Botanical and*

Geographic Origin within *Purity and Authenticity*. The commenters indicated that the language "physicochemical, and microscopic characteristics" is unclear without definitions for these characteristics. The commenters noted that specific characteristics should be named, and if there are no other specified characteristics, only pollen should be cited as the characteristic, along with deletion of the term "microscopic characteristics."

Response: Comment not incorporated. Additional microscopic characteristics may include, but are not limited to, small air bubbles or very fine particulate matter. The terms used are consistent with the terminology used in other global standards and accurately convey the characteristics that may be referred to as part of optional supplementary information.

Comment Summary #35: A comment was received requesting removal of the labeling instructions in *Botanical and Geographic Origin* within *Purity and Authenticity*. Alternatively, the commenter requested that the labeling instructions be revised to simply indicate compliance with FDA labeling requirements.

Response: Comment not incorporated. The current text is intended for global use and does not conflict with, or prevent the use of the current version of the FDA labeling guidance for honey, which does not address geographic origin labeling.

Comment Summary #36: A comment was received requesting a revision to the section *Foreign Sugars* within *Purity and Authenticity*. The commenter suggested the addition of the following statement before the last sentence prior to the bulleted list: "Taken individually, these methods are not capable of detecting the full range of adulterants currently in use within the market. The best practice is to apply more than one, perhaps all, given the origin and risk analysis for that region. Depending upon the type and sophistication of the adulterant syrups, some of the methods below are unable to detect the adulteration or can only detect adulteration at levels as high as 30-40%."

Response: Comment partially incorporated. The section was revised to state the following (underline added to indicate specific wording applied by the Expert Committee decision that deviated from the commenter's suggestion): "Taken individually, these methods are not capable of detecting the full range of adulterants and modes of honey adulteration currently in use within the market. The best practice is to apply more than one, perhaps all, given the origin and risk analysis for that region. Depending upon the type and sophistication of the adulterant syrups, some of the methods below are unable to detect the adulteration or can only detect adulteration at levels as high as 30-40%."

Comment Summary #37: Five comments were received requesting the removal of NMR, EA/LC-IRMS, and LC-HRMS analysis within *Purity and Authenticity*.

Response: Comment not incorporated. *Additional Considerations* do not have acceptance criteria associated with them and are merely suggestions. Additional guidance is under development to assist users in incorporating these types of highly technical instrumental techniques.

Expert Committee-initiated change #1: The statement "Drying of honey requires ample space in the hive" was revised to state "Drying of honey requires ample space in the hive and is considered completed by the bees once the honey is capped" (underlined text added) in an effort to describe the process accurately and clearly.