Commentary

Food Chemicals Codex (FCC), Tenth Edition, Second Supplement

March 1, 2017

In accordance with USP's provisionally approved Rules and Procedures of the 2015-2020 Council of Experts (CoE Rules), and except as provided in Section 8.01(e) Immediate Standards, 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 on the Commentary section of the USP.org website 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 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):

- Appendix VIII: Oleoresins Residual Solvent (Oleoresins)
- Hesperidin
- Methyl 2-Nonenoate
- Trans-Resveratrol, Fermentation (Saccharomyces Cerevisiae)

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

- Ascorbyl Palmitate
- Ascorbyl Stearate
- Benzyl Acetoacetate
- Bisabolene
- Disodium Guanylate
- Monoammonium Glycyrrhizinate
- Neotame
- Octyl Gallate
- Potassium Phosphate, Dibasic
- Potassium Phosphate, Monobasic
- Potassium Phosphate, Tribasic
- Potassium Saccharin

Monograph/Sections: Appendix VIII: Oleoresins Residual Solvents (Oleoresins)/Multiple Sections
Expert Committee: Food Ingredients
Number of comments: 7

General
Comment Summary #1: The commenter requested replacing the word "hexane" with "hexanes" throughout the standard and providing retention times for all hexanes in *Table* 2, because the term "hexanes" and their retention time might be more accurate.
Response: Comment not incorporated. The Expert Committee noted that replacing "hexane" with "hexanes" and providing the retention times for each hexane isomer (if present) would require additional data.

Standard stock solution A
Comment Summary #2: The commenter requested replacing the word "trichloromethylene" with "trichloroethylene," because it is the incorrect chemical name.
Response: Comment incorporated.

Chromatographic system

Comment Summary #3: The commenter requested inserting a period after "d" in "i.d" in *Column* and replacing the title for *Table 1* with "*Column temperature program*,"
Response: Comment not incorporated. The existing text already has the period after "d" and the title for *Table 1* is as requested.
Comment Summary #4: The commenter suggested inserting a parenthesis in front of "r_{ss}" in the formula.
Response: Comment not incorporated. The existing text already has the parenthesis as requested.

Gas flow
Comment Summary #5: The commenter proposed using helium or hydrogen as a carrier gas instead of the existing nitrogen, because nitrogen is not the most efficient option as a carrier gas due to its lower diffusivity.
Response: Comment not incorporated. The suggested revision may be considered for future *FCC Forum* publication if adequate supporting data and information are submitted.

Analysis
Comment Summary #6: The commenter proposed replacing "*Sample solution A*" with "*Sample solution*" in the *Analysis* section because it is not the correct solution required for "r_U" to calculate the *Result (%)*.
Response: Comment incorporated.
Comment Summary #7: The commenter requested replacing the result unit with "ppm" or "mg/g" instead of the existing %, because the solutions used are expressed in mg/L.
Response: Comment not incorporated. The existing limits for residual solvents are expressed in percent (%) in the *FCC* Spice Oleoresins monograph.

Expert Committee-initiated Change #1: In *Table 2* and throughout the standard, the term "Methyl Chloride" was replaced with "Methylene Chloride."

Monograph/Section: Methyl 2-nonenoate/Description
Expert Committee: Food Ingredients
Expert Committee-initiated Change #1: In the *Description* section, include the following statement: "It is typically produced by distillation process" to more accurately represent the ingredient's manufacturing process.

Monograph/Sections: *Trans*-Resveratrol, Fermentation (*Saccharomyces cerevisiae*)/Multiple Sections
Expert Committee: Food Ingredients
Comment Summary #1: The commenter suggested changing the title of the monograph to "*trans*-Resveratrol, Fermentation (*Saccharomyces cerevisiae*)" to be specific to the material produced as described in the *Description* and the accompanying specifications and methods. The commenter noted that the specifications within the proposed monograph may not be appropriate for ingredients manufactured using other processes or reagents. In particular, impurity profiles and related compounds would be

expected to differ based on the method of manufacture. Supporting information on impurities in ingredients produced via fermentation versus a plant-derived product was provided.
Response: Comment incorporated.
Comment Summary #2: The commenter suggested that USP use a unified monograph approach that would cover multiple processes/sources for *trans*-resveratrol in a single monograph using the title originally proposed (*"trans*-Resveratrol"). Differences in quality parameters and appropriate analytical techniques based on route of synthesis could be added, as needed, using the "type" designation approach where each "type" represents a specific method of manufacture.
Response: Comment not incorporated. Currently there are no existing monographs for *trans*-Resveratrol in *FCC*; therefore, it is not necessary to incorporate different "types" of the ingredient in the existing proposal.
Expert Committee-initiated Change #1: The name of the USP Resveratrol RS was changed to USP *trans*-Resveratrol RS in all instances that it appeared in the proposed monograph to remain consistent with USP Reference Standard nomenclature policies.
Expert Committee-initiated Change #2: A note indicating that all samples should be stored at 5° after preparation until they are injected into the chromatograph (including samples in an autosampler) was added to the *Assay* based on information and data submitted.

Monograph/Section(s): Hesperidin/Description
Expert Committee: Food Ingredients
Expert Committee-initiated Change #1: The word "aqueous" was added to the sentence "Hesperidin occurs as a white or light brown to yellowish crystalline powder that consists of a bioflavonoid that is produced by aqueous extraction of citrus fruits" to indicate the solvent being used for extraction.
Expert Committee-initiated Change #2: The function of hesperidin was changed from "antioxidant" to "source of flavonoid."