USP Guideline for Submission of Revisions to the *Food Chemicals Codex*

1. INTRODUCTION AND PURPOSE

Revision of the *Food Chemicals Codex* (*FCC*) is a process that is both continual and necessary for maintaining an up-to-date compendium that accurately reflects innovations in the manufacture and use of food ingredients and development of new food ingredients. Because the *FCC* is revised through an open and transparent process, specific documentation of each proposed revision – whether it is to a monograph or to a test method – is required. The purpose of this document is to provide guidance to stakeholders interested in submitting proposed revisions to the *FCC* by describing the *FCC* revision process and detailing the elements required in a proposed revision. All such requests shall be handled in accordance with Section 8.01(a) – (e) and other provisions of the 2015-2020 Rules and Procedures of the Council of Experts (CoE Rules), which govern all aspects of *FCC's* standards-setting processes. Stakeholders submitting revision proposals should understand that the public standard developed from any proposal may incorporate comments from other stakeholders and in all cases the text of the final standard will ultimately be decided by the Food Ingredients Expert Committee (FIEC), the volunteer body responsible for the standards-setting activities of the *FCC*.

2. *FCC* REVISION PROCESS

The *FCC*'s standards-setting process is open and transparent and public participation is encouraged. A revision is a request by a Sponsor (i.e., stakeholder from industry, academia, regulatory body or any other interested stakeholder) to change the content of the *FCC* and must be made to an *FCC* Scientific Liaison ("Liaison"). The Liaison is a USP scientist who serves as a link between the Sponsor, public and the FIEC. The Liaison will work with the Sponsor of the revision to ensure that the Sponsor's submission contains the appropriate information and data required to initiate and complete the *FCC* revision process.

The revision process begins when the *FCC* Liaison receives a communication from a Sponsor indicating that a revision to the *FCC* is necessary. This initial contact may be in any format, but emailed communications are typically the preferred means of submitting a proposed revision. The contact information for FCC staff is available online at www.usp.org/fcc/forum/staffDirectory.html.

Once the Liaison receives a request to make a revision to the content of the *FCC*, they will work with the Sponsor to gather the information and data required for the FIEC to consider the revision proposal. When all of the information and supporting data has been provided to the Liaison, the Liaison makes the determination on whether or not the revision is ready to be published on the *FCC Forum* for public comment. The *FCC Forum* is an online platform for providing public notice of revisions to the *FCC* and receiving public comment. The *Forum*

EFFECTIVE DATE: 06/24/2016

publishes twice annually via the *USP* website.(https://fccforum.usp.org) The *FCC Forum* is free and open to the public and opens on the last day of June and the last day of December every year. Interested stakeholders may submit comments to the *FCC Forum* for a period of 90 days. Comments received may be used to alter the text of the revision and are always considered by the FIEC before voting to adopt, modify, or reject the revision. For more information about the *FCC's* standards-setting process for new monographs, please also refer to the *Guidelines for Submissions of New Food Ingredient Monographs to the FCC*.

3. SUBMITTING A REVISION PROPOSAL

3.1 Overview

All submissions for revisions to the *FCC* must be accompanied by the following information and documentation, including but not limited to, the items listed below that are necessary for supporting the proposed revision:

1. The text of the proposed revision;
2. The rationale for the proposed revision;
3. Supporting data for the proposed revision; and,
4. A description of the regulatory impact (if any).

A proposed revision to the *FCC* must be emailed or mailed directly to the Liaison responsible for the monograph or section of the *FCC* being revised. In order to identify the Liaison responsible please contact the *FCC* staff at fcc@usp.org.

3.2 Text of Revision

All proposals to revise a particular section of the *FCC* should include the text of the proposed revision. Sponsors must be specific when proposing revisions, including naming the monograph or test procedure (and *FCC* Appendix, where applicable) to be revised and providing the exact text additions and deletions that are proposed to be made. Proposals for revisions must refer to the current edition of the *FCC* and must provide the monograph title, and headings/subheadings under which the revision is being proposed. It is most helpful to *FCC* staff if the text of the revisions is written in current *FCC* format.

3.3 Rationale for Revision

Sponsors must provide the rationale for proposing the revision to the FCC. The Sponsor may include scientific, economic, or other reasons for proposing a revision to

the *FCC*. Some examples of reasons that may be given to request a revision include but are not limited to, the following:

- Changes in the method of manufacture of a food ingredient necessitate changes to the monograph description or additions/deletions of impurity specifications;
- Modernization of test procedures referenced in a monograph or an *FCC* Appendix; require updating or replacing of old methods
- Inaccuracies have been identified with an existing test procedure or monograph requiring replacement or revision;
- An existing test method is difficult and/or costly to run and a sufficient replacement method has been identified; and,
- Existing Identification procedures have been shown to be insufficient in differentiating the food ingredient from a specific adulterant, necessitating additional or different methods.

Because it can be costly for laboratories to implement new or revised test methods, a proposal to revise *FCC* test methods should represent a significant change from the existing method. Supporting documentation of the rationale must be provided to the Liaison with the submission of the proposed revision. This documentation may take many forms, but it must include data to support the need for the revision being claimed by the Sponsor.

3.4 Supporting Data

All proposals to revise an existing monograph or Appendix in the *FCC* must include the necessary supporting data. Proposed revisions to monograph specifications for a food ingredient must be submitted with supporting data from at least three representative, food-grade batches of the ingredient. Proposed revisions to test methods within a monograph must be submitted with method validation data if the revision concerns the addition of a new method (or a substantial change to the existing method) and with supporting data from food-grade batches of the ingredient. Similarly, proposed revisions to Appendix test methods must be submitted with method validation when necessary and with supporting data from affected monograph ingredients. For more complete information regarding method validation requirements, please refer to *Validation of Food Chemicals Codex Methods* in the *General Information* section of *FCC*. In all cases, a revision to a test method must be submitted with data comparing the existing method to the new or revised method. The Liaison assigned to the *FCC*

EFFECTIVE DATE: 06/24/2016

monograph or Appendix revision will inform the Sponsor if further data is necessary to support of the proposed revision.

3.5 Regulatory Implications

Some of the food ingredient monographs in the *FCC* are referenced in regulatory documents, including in the *Code of Federal Regulations (CFR)* of the United States (. If a proposed revision to an *FCC* monograph has any known regulatory implications, it is the responsibility of the Sponsor to include this information in the submission of the proposed revision. Information regarding the affected country and the applicable regulation must be submitted, along with details of any actions being taken to revise the regulation itself. In cases where the *CFR* cites an older version of the *FCC* than the current effective version, the Liaison must be informed. The Liaison will indicate to the Sponsor whether an FDA representative must be involved in the proposed revision to the *FCC*.

4. CONFIDENTIALITY, DOCUMENT DISCLOSURE AND INTELLECTUAL PROPERTY POLICIES

USP has established policies and rules that provide the highest safeguards to confidential information submitted by Sponsors during the course of the standards-setting process. USP's confidentiality policies and the CoE Rules require both USP expert volunteers and staff involved in USP's standards-setting process to maintain the confidentiality of information submitted to USP by a third party. Below is a brief summary and link that provides additional information on each of the specific policies, provisions of the CoE Rules, and procedures concerning confidentiality.

4.1 USP Code of Ethics Confidentiality Policy

The USP Code of Ethics (http://www.usp.org/ethics) applies to USP employees, expert volunteers and representatives. The Confidentiality Policy in the USP Code of Ethics obligates everyone at USP to protect confidential information and proprietary information, whether generated by USP or by third parties, unless disclosure is authorized or legally mandated. All information about USP and our compendial activities is considered confidential unless it is made publicly available by USP or it is known to be publicly available outside of USP.

Confidential information consists of information that is not available to or intended for the public to view and can fall within, but is not limited to, the following categories:

- financial, scientific or medical information; customer information;

- supply and service information; marketing information;
- correspondence between and among USP staff and members of its Board of Trustees, Council of Experts, and Expert Committees;
- personnel or consultant files;
- trade secrets; and,
- confidential information relating to manufacturing processes and other information which USP or a third party may deem confidential.

USP's confidentiality policy does not apply when a third party's information is required to be disclosed by law, regulation, rule, act or order of any governmental authority or agency, such as identifying country of origin on USP reference materials.

4.2 USP CoE Rules and Confidentiality

The CoE Rules (http://www.usp.org/about-usp/leadership/policies-rules/rules-procedures-council-experts) reinforce the obligation of USP expert volunteers to maintain confidentiality during their standards-setting activities. Under Rule 2.06, CoE and EC members must maintain the confidentiality of all information they receive during the standards-setting process and are prohibited from disclosing any information for any purpose unless the information is already publicly available. **In cases of doubt as to the confidentiality of information, the information in question must be treated as confidential unless otherwise shown.** Under Rule 6.02, government liaisons to such Expert Committees and Expert Panels also have access to such information and are permitted to use it only for USP standards-setting purposes. USP expert volunteers and government liaisons sign a confidentiality agreement with USP reflecting these obligations.

4.3 USP Document Disclosure Policy

Under USP's Document Disclosure Policy, which is a part of the Code of Ethics, USP provides disclosure of information and records regarding USP standards-setting activities to third parties upon request consistent with:

- The rights of individuals to privacy
- USP's need to protect the confidentiality of trade secrets and other proprietary commercial or financial information
- USP's need to promote frank internal deliberations and to pursue standards-setting activities without disruption

USP will not disclose any document containing trade secrets or confidential commercial secrets, if such documents have been specifically designated as such when submitted to USP. Accordingly, sponsors should indicate in their Request for Revision whether any of the submitted documents or other information should be treated as confidential. Any submitted documents not clearly marked confidential will be subject to disclosure under the Document Disclosure Policy. As a general policy, USP undertakes to keep sponsor names confidential when providing documents under the Document Disclosure Policy, but USP reserves the right to disclose the identity of a sponsor at its discretion if circumstances warrant.

4.4 Intellectual Property

At times, issues of intellectual property arise regarding a monograph. Under USP's Intellectual Property Policy, available on USP's Website, USP respects intellectual property rights and uses its best efforts to adhere to all applicable laws regarding USP protection of intellectual property. USP is not, however, responsible for the protection or enforcement of intellectual property rights in the U.S. and elsewhere, and because USP's standards are intended to be public standards available for the use and benefit of all parties, USP requests that sponsors disclose in their Requests for Revision whether any portion of the methods or procedures submitted is subject to patent or other sponsor-held intellectual property rights. In cases where patented methods, procedures or materials required for compendial tests and assays (such as RS or photomicrographs) are proposed, USP may seek assistance from the sponsor in obtaining clearance or license for use by any persons seeking to use or apply a USP public standard incorporating such method, procedure or material, and may consider other approaches including the solicitation of other Requests for Revision that use

alternative methods or procedures. USP reserves the right to indicate in a resulting monograph or general chapter whether methods or procedures are subject to such intellectual property rights.

This Guideline supersedes any previous guideline issued by USP on Submission of Revisions to the Food Chemicals Codex.