

# USP Guideline for Submitting Proposals for Revisions to the *Food Chemicals Codex*

## 1. INTRODUCTION

Revision of the *Food Chemicals Codex (FCC)* is a process that is both continual and necessary for maintaining a compendium that accurately reflects changes in the manufacture and use of food ingredients and development of new ingredients. Because the *FCC* is revised through an open and transparent process, specific documentation of each proposed change – whether it is to a monograph, to acceptance criteria, or to a test method – is required. The purpose of this document is to provide guidance to parties interested in submitting proposed revisions to the *FCC* by means of describing the *FCC* revision process and detailing the required elements of a proposed revision. Parties submitting revision proposals should understand that the public standard developed from any proposal may incorporate comments from other parties and in all cases the text of the final standard will ultimately be decided by *FCC*'s Food Ingredients Expert Committee.

## 2. REVISION PROCESS

All changes in the scientific content of the *FCC* are made through an open and transparent revision process and participation in this process by outside experts and interested parties is encouraged. Requests to change the content of the *FCC* should be made to a Scientific Liaison for the *FCC*. The Scientific Liaison is a USP scientist who serves as a link between the public and the Food Ingredient Expert Committee (the Committee), the volunteer body responsible for the standards-setting activities of the *FCC*. The Scientific Liaison will work with the party submitting the requested revision (the Sponsor) to ensure that the revision proposal contains the appropriate information and data, and then shepherd the proposal through *FCC*'s revision process.

Scientific Liaisons receive requests to revise the *FCC* from several types of Sponsors. Sponsors are often from industry, academia, or regulatory bodies, but any interested stakeholder who can provide the information and data necessary for requesting a revision may do so. The revision process begins when the Scientific Liaison receives a communication from a Sponsor indicating that they believe 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 proposal. Contact information for all members of FCC staff is available online at [www.usp.org/fcc/forum/staffDirectory.html](http://www.usp.org/fcc/forum/staffDirectory.html).

Once the Scientific Liaison receives a request to make a change to the text of the *FCC*, they work with the Sponsor to gather the elements required for a revision proposal. When all of the information and supporting data has been supplied to the Liaison they make the determination that the proposal is ready to proceed to the *FCC Forum*. The *FCC Forum* is the online platform for proposing revisions to the *FCC*. The *Forum* publishes twice annually via the *FCC* website. It is free and open to the public and opens on the last day of June and the last day of December every year. Interested parties 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 Committee before voting on a proposed revision.

For more complete information about our Revision Process, please also refer to the Guidelines for New Submissions.

### **3. SUBMITTING A REVISION PROPOSAL**

#### **3.1 Overview**

All revision proposals should be accompanied by some basic information and documentation, including the items listed below. Please include all items necessary for supporting the proposed revision.

1. The text of the proposed revision
2. Rationale for the proposed revision
3. Supporting data for the proposed revision
4. Regulatory implication information (as necessary)

The proposed revision should 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, Sponsors who have subscriptions to the *FCC Online* should refer to the bottom of the listing they wish to revise. If you do not have access to the *FCC Online*, please contact us at [fcc@usp.org](mailto:fcc@usp.org) and we will help you determine the appropriate Liaison to whom your revision should be submitted.

#### **3.2 Text of Revision**

All proposals to revise a section of the *FCC* should start with the text of the proposed revision. Sponsors are asked to be as specific as possible when proposing revisions, including naming the monograph or test procedure (and Appendix, where applicable) to be changed and giving the exact text additions and deletions that should be made. Please refer to the current edition of the *FCC* when proposing a revision, clearly giving the page number, monograph title, and headings/subheadings under which the revision is being proposed. It is most helpful if the text of revisions is written in current *FCC* format.

#### **3.3 Rationale for Revision**

Whenever a revision is proposed to existing text in the *FCC*, Sponsors are required to give their rationale for proposing the revision. The Sponsor may have scientific, economic, or other reasons for proposing revisions to the *FCC*. Some examples of the reasoning for requesting a revision are given below:

- Changes in the method of manufacture of an ingredient necessitate changes to the description or additions/deletions of impurity specifications
- Modernization of test procedures referenced in a monograph or 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
- Existing Identification procedures have been shown to be insufficient in differentiating the ingredient from a specific adulterant, necessitating additional or different methods

Because it can be costly for laboratories to implement new or revised test methods, proposed revisions to test methods should represent a significant change from the existing method. Supporting documentation of the rationale should be provided to the Liaison with the submission of the proposed revision. This documentation may take many forms, but it should lend evidence to the claim being made by the Sponsor.

### **3.4 Supporting Data**

All requests to revise an existing monograph or Appendix in the *FCC* should have included the necessary supporting data. Proposed changes in specifications for an ingredient should be submitted with data from at least three representative, food-grade batches of the ingredient that supports the proposed revision. Proposed changes to test methods within a monograph should be submitted with method validation data if the revision is 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 changes to Appendix test methods should 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, revision to a test method should be submitted with data comparing the existing method to the new or revised method. Whenever necessary, the Liaison assigned to the monograph or Appendix will indicate if further data is necessary in support of the proposed change.

### **3.5 Regulatory Implications**

Many of the ingredient monographs in the *FCC* are referenced in regulatory documents, including in the Code of Federal Regulations of the United States (CFR). If a proposed change 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 country and regulation applicable should be

submitted, along with details of any actions being taken to change the regulation itself. In cases where the CFR cites an older version of the *FCC* than the current effective version, please inform the Liaison, who will indicate when an FDA representative should be involved in the proposed revision to the *FCC*.

#### **4. INTELLECTUAL PROPERTY CONSIDERATIONS AND DOCUMENT DISCLOSURE**

At times, issues of timing and intellectual property arise regarding a monograph. *USP follows the laws of the U.S. and other foreign countries regarding protection of intellectual property.* Under USP's Intellectual Property Policy, available on USP's website, USP respects intellectual property rights and adheres to all applicable laws regarding protection of intellectual property. A Sponsor may specifically request that certain portions of a Request for Revision be kept confidential. This request will be honored, and the designated confidential information will be exempt from disclosure under USP's Document Disclosure Policy, also available on the USP website.

If you have more questions, please contact the USP Food Ingredients Group at [fcc@usp.org](mailto:fcc@usp.org) or 301-881-0666.