

USP Guideline for Submitting Proposals for New Monographs to the *Food Chemicals Codex*

1. INTRODUCTION

The *Food Chemicals Codex (FCC)* is constantly revised and modernized through an open and transparent process. Many proposed changes to the *FCC*, including new monograph submissions, are submitted to FCC scientific staff by contacts from industry, academia, regulatory bodies or any other interested party referred to in this document as Sponsor. The member of the FCC scientific staff who serves as a link between Sponsors and the Food Ingredient Expert Committee (the Committee - the body of volunteers responsible for the standards-setting activities of the *FCC*) is called a Scientific Liaison or simply a Liaison.

The purpose of this document is to provide basic guidance to Sponsors for the preparation of new monograph submissions in order to facilitate development and completion of a monograph proposal. Sponsors 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 – NEW MONOGRAPHS

All changes in the scientific content are made through an open and transparent revision process and participation in this process by outside experts and interested parties is encouraged. All requests to add a new monograph are assigned to a Scientific Liaison for the *FCC*. The Liaison will work with the Sponsor to ensure that the monograph proposal contains the appropriate information and background materials, and then shepherd the proposal through *FCC's* revision process.

Revisions to the *FCC* are proposed through the *FCC Forum*, which publishes twice annually via our website¹. The *FCC Forum* is free and open to the public and serves as a platform for proposing revisions to the content of the *FCC*, including addition of new monographs. The *Forum* opens on the last day of June and the last day of December. Once open interested parties may review proposed revisions, including new

¹ www.forum.foodchemicalscodex.org

monographs and tests and changes to existing monographs and tests and comment on the proposals. The comment period is 90 days from the opening of the *Forum* and all comments made are received directly by the Liaison responsible for the ingredient. Comments received may be used to alter the text of the adopted proposal and they are always considered by the Committee before balloting on a proposal.

To ensure that a proposal appears in the *FCC Forum* in a timely manner, it should be complete and include all supporting information and data relevant to the submission (see below for necessary information). Please submit any request to develop a new *FCC* monograph to FCC staff via email or standard mail. Contact information for FCC staff is listed online at www.usp.org/fcc/forum/staffDirectory.html.

For more complete information on our Revision Process, please refer to the [Guidelines for Revisions](#).

3. SUBMITTING A NEW MONOGRAPH PROPOSAL

3.1 Overview

All proposals to add a new monograph to the FCC should be accompanied by some basic information and documentation, including the items listed below.

1. Documentation of the regulatory status (domestic or international) of the ingredient and, if possible, a copy of any application or dossier previously submitted to a regulatory agency for the purposes of approval/assessment
2. Technical details for the ingredient (not required)
3. Proposed information for each appropriate monograph section
4. Supporting data for all proposed specifications
5. Method validation(s) for all proposed test procedures including all relevant test parameters

3.2 Regulatory Documentation

Ingredients appearing in the FCC must be permitted for use in foods or in food processing either in the United States or internationally. New monograph proposals should include documentation regarding the regulatory status of the ingredient pertaining to its use in foods. This documentation may be provided to FCC in several formats, including:

- CFR citations for approved food or color additives in the United States
- Generally Recognized as Safe (GRAS) documentation, whether in the form of a formal Petition or Notification sent to the FDA or as the report created by a GRAS panel for a self-determined GRAS ingredient
- FDA responses to GRAS Petitions or Notifications
- Color Additive Petitions
- Food Additive Petitions
- Documentation of approval in other countries (or sanction by an international regulatory body)

In all cases, it should be noted if the substance has been evaluated by JECFA and full specifications exist.

3.3 Technical Details

To aid USP scientific staff and the Committee in the evaluation of proposed specifications, relevant information on the method of manufacture and chemical composition of the food ingredients should be submitted whenever possible. Method of manufacture information should include the principle(s) of the manufacturing process and a description of the manufacturing process including any intermediates. Chemical compositional information should provide a characterization of the food ingredient sufficient to distinguish it from other similar food ingredients, including all available information on potential impurities and degradation products usually occurring in or arising from the method of manufacture employed.

While submission of the additional technical details is voluntary, it can aid the Committee in deciding whether or not the proposed monograph is comprehensive and merits inclusion in the *FCC*.

3.4 Intellectual Property Considerations and Document Disclosure

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.

3.5 Draft Monograph Elements

3.5.1 Title and Chemical Information

A proposed title should be non-proprietary, preferably established by national legislation or used by international bodies. In the absence of these, the title may be chosen from existing common or trivial names and should be distinctive enough to enable the substance to be clearly distinguished from other food ingredients. Synonyms for the ingredient should be listed under the title and should account for all alternative names used in commerce and by regulatory authorities. The nomenclature used for flavoring agents may not be consistent with other authoritative sources.

Chemical information should be included directly under the title and synonyms list. This information includes the following elements when applicable: molecular structures, chemical formulas, formula weights, and applicable registry numbers such as those determined by CAS², FEMA³, and INS⁴. If multiple registry numbers are relevant, please include all of them.

² CAS: Chemical Abstract Service

³ FEMA: Flavor and Extract Manufacturers' Association of the United States

⁴ INS: Codex International Numbering System for Food Additives (Codex Alimentarius Commission CAC/GL 36-1989)

3.5.2 Description

Characteristics described and statements made in the *DESCRIPTION* section of a monograph are not requirements, but are provided as information to users of the compendium. It often includes information on the origin of the substance and a brief description of the method of manufacture. The physical characteristics, such as color and form, of the specified substance are described and information on its stability under certain conditions of exposure to air and light may also be presented. Statements in this section also commonly indicate approximate physical properties of the ingredient such as solubility in various solvents, pH, melting point, and boiling point, with numerical values modified by “about,” “approximately,” “usually,” “~,” and other comparable nonspecific terms. The presence of other substances intentionally added in commercial preparations should also be indicated, as appropriate.

3.5.3 Function

This section is also given for information only and not intended to limit in any way the choice or use of the substance or to indicate that it has no other utility, nor should the *FCC* be seen as endorsing any specific use of the ingredient. A statement of function is provided to indicate the principal technical effect(s) of the substance in foods or in food processing (e.g., emulsifier) or a principal application such as “Nutrient”. The terms used should be harmonized with those used in the most recent revision of the Codex Alimentarius *Class Names and International Numbering System for Food Additives* (CAC/GL 36-1989), with those listed in the U.S. Code of Federal Regulations (21 CFR 170.3(o)) or with existing *FCC* monographs of similar ingredients if they exist.

3.5.4 Packaging and Storage

This section is advisory only and should provide statements describing the appropriate care for packaging and storage and emphasize instances where deterioration could be accelerated under adverse packaging and storage conditions, such as exposure to air, light, or temperature extremes, or where safety hazards are involved. Additional discussion is provided in the *General Provisions and Requirements Applying to Specifications, Tests, and Assays of the Food Chemicals Codex*.

3.5.5 Identification

The tests described under this heading are designed for application to substances taken from labeled containers and are provided as an aid to substantiate identification of a labeled ingredient. These qualitative or quantitative tests may not be sufficient to establish proof of identity, but failure of a substance taken from a labeled container to meet the requirements of a prescribed identification test indicates that the ingredient does not conform to the requirements of the monograph.

Proposed new monographs should contain as many identification tests as necessary to differentiate the ingredient from similar components and, whenever possible, detect the presence of relevant potential adulterants. Chromatographic and spectroscopic (infrared and ultraviolet) tests are common identification methods, and the use of a

reference material may be indicated. The *General Tests and Assays* section of the *FCC* contains test procedures that may be applicable for a proposed new monograph.

3.5.6 Assay

Tests in this section provide a means of assessing the amount of the principal functional component(s) present in the food ingredient. This test (or tests) shall be quantitative and accompanied by a proposed minimum acceptable content or acceptable content range of the component. Typical *FCC* methods are titrimetric and chromatographic methods. Any required treatment of the sample should be clearly outlined and all calculations should contain adequately defined terms and variables with relevant units included. Whenever possible the Assay should utilize comparison to an authenticated reference material (to be developed by USP). The *General Tests and Assays* section of the *FCC* contains test procedures that could be applicable for a proposed new monograph.

3.5.7 Impurities

Test procedures and acceptance criteria for inherent trace impurities are provided to limit such substances to levels that are consistent with good manufacturing practice and that are safe and otherwise unobjectionable under conditions in which the food substance is customarily used. Sponsors should include impurity methods and limits based on their knowledge of all known manufacturing process by which an ingredient is produced and the raw materials used in that process. The *FCC* distinguishes impurities as either **Inorganic Impurities** or **Organic Impurities**. In most cases the Committee expects any new monograph submission to include a limit for lead because of the prevalence of this impurity in ingredients and the associated health risks.

3.5.8 Specific Tests

This section contains tests that do not clearly fall under any of the other sections of a monograph. They are included to provide a better description of the food ingredient, to ensure that the ingredient can be clearly distinguished from another, similar ingredient, and to minimize the opportunity for adulteration of the ingredient. In addition to any proposed tests unique to the food ingredient, the appendices in the *FCC* contain a number of general analytical procedures that may be appropriate as “specific tests”, such as Loss on Drying, Residue on Ignition (Sulfated Ash), Acid Value, Iodine Value, and Viscosity.

3.5.9 Other Requirements

In some instances, a new monograph will need to include a requirement that is clearly inappropriate for any of the other sections of the monograph. Where a labeling requirement is needed, it should be included under *Other Requirements*. Instances where a labeling requirement is appropriate include monographs that specify more than one type of material, for instance solutions which may be sold in multiple concentrations.

For more complete information regarding the elements of a draft proposed monograph, please refer to the [Summary Table of Required Documents](#) .

4. DATA FOR SUBMISSIONS TO FCC

4.1 Supporting Data

For all proposed acceptance criteria in a new monograph, supporting data should be presented from at least three independent and representative production batches. Such data can often be obtained from certificate of analysis documentation.

4.2 Method Validation

A new monograph proposal including test procedures not currently contained in the *FCC* should be accompanied by the appropriate method validation package. A typical method validation package addresses some or all of the following parameters: specificity, linearity, range, limit of detection, limit of quantitation, ruggedness, robustness, accuracy, and precision. The data and information included in this package can vary depending on the type of test method involved. The section on *Validation of Food Chemicals Codex Methods* in the *FCC* provides a detailed discussion to assist in identifying necessary validation parameters.

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