

Guideline on *Food Chemicals Codex* "Provisional Monographs" for Self-Affirmed GRAS Ingredients

Version 1.0

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1. Background

Within the United States (U.S.) regulatory food law, food ingredient manufacturers have several options to legally use food substances in food production. A popular option is the "GRAS self-affirmation" process, in which food manufacturers can follow a rigorous safety assessment of a proposed food substance and self-affirm the GRAS (Generally Recognized As Safe) status of such a substance for an intended use using a panel of qualified experts. This process is exclusively the responsibility of the manufacturer seeking the self-affirmed GRAS status, and although the U.S. Food and Drug Administration (FDA) does not register or review such claims it does recognize the status and allow self-affirmed GRAS ingredients to be used in foods.

While self-affirmed GRAS status has been recognized by the FDA since the proposed rule describing it was published in 1997, the *Food Chemicals Codex (FCC)* previously has not had a mechanism specifically designed to establish monographs for food ingredients that have not undergone review by the FDA or other international regulatory authorities. To include a new food ingredient monograph in the *FCC*, USP typically requests a statement from the monograph sponsor of the ingredient's regulatory approval for use in a recognized regulatory authority, but such a statement is not available from the FDA for self-affirmed GRAS food ingredients. The purpose of the provisional monograph process is to permit the development of quality specifications for a food ingredient that would otherwise be unknown. These provisional monographs will be maintained in a special section of the *FCC* that distinguishes them from monographs for food ingredients that have received regulatory approval.

2. Requirements

In general, the submission requirements for a provisional *FCC* monograph do not differ from the requirements for a "standard" monograph except for the following:

(1) a summary of the self-affirmed GRAS status report is required to be submitted in lieu of a statement of regulatory review and approval.

For information regarding USP's requirements for submission of a new monograph please see: Guideline For Request

3. Process

A provisional monograph will be developed through the same public vetting process as a "standard" monograph, which includes notice and a public comment period. However, if

during the provisional monograph development process or after its publication, USP is informed that the food ingredient has been approved by a regulatory authority, USP will move the provisional monograph to the "standard" monograph section in *FCC*.

For information regarding USP's standard revision process, which includes a proposed new monograph please see: [Guidelines For Revisions](#)