



USP Guideline on Use of Accelerated Processes for Revisions to the *Food Chemicals Codex*¹

Background:

The Rules and Procedures of the Council of Experts (Rules)² specify various processes (Accelerated Revision Processes) that can be used to make revisions to the *Food Chemicals Codex (FCC)* effective more quickly than through USP's standard process (Standard Revision Process). USP's Standard Revision Process calls for publication of a proposed revision in the *FCC Forum (FF)* for a 90-day notice and comment period and, after the revision is approved by the relevant USP Expert Committee, publication in the next *FCC* or *Supplement*, as applicable. Accelerated Revision Processes, which include *Errata*, *Expedited Standards* and *Immediate Standards*, do not always require notice and comment and allow for a revision to become effective prior to the next published *FCC* or *Supplement*.³

The purpose of this Guideline is to delineate the circumstances under which these Accelerated Revision Processes are utilized. The Decision Tree that follows specifies the criteria applied by USP in considering whether an Accelerated Revision Process is appropriate. The footnotes to the Decision Tree provide additional explanation for applying the criteria outlined in the Decision Tree, and further clarification as to when an Accelerated Revision Process rather than the Standard Revision Process should be utilized.

This Guideline also addresses the use of delayed effective dates for revisions made through the Standard Process, where such revisions have broad industry impact and require additional time to implement.

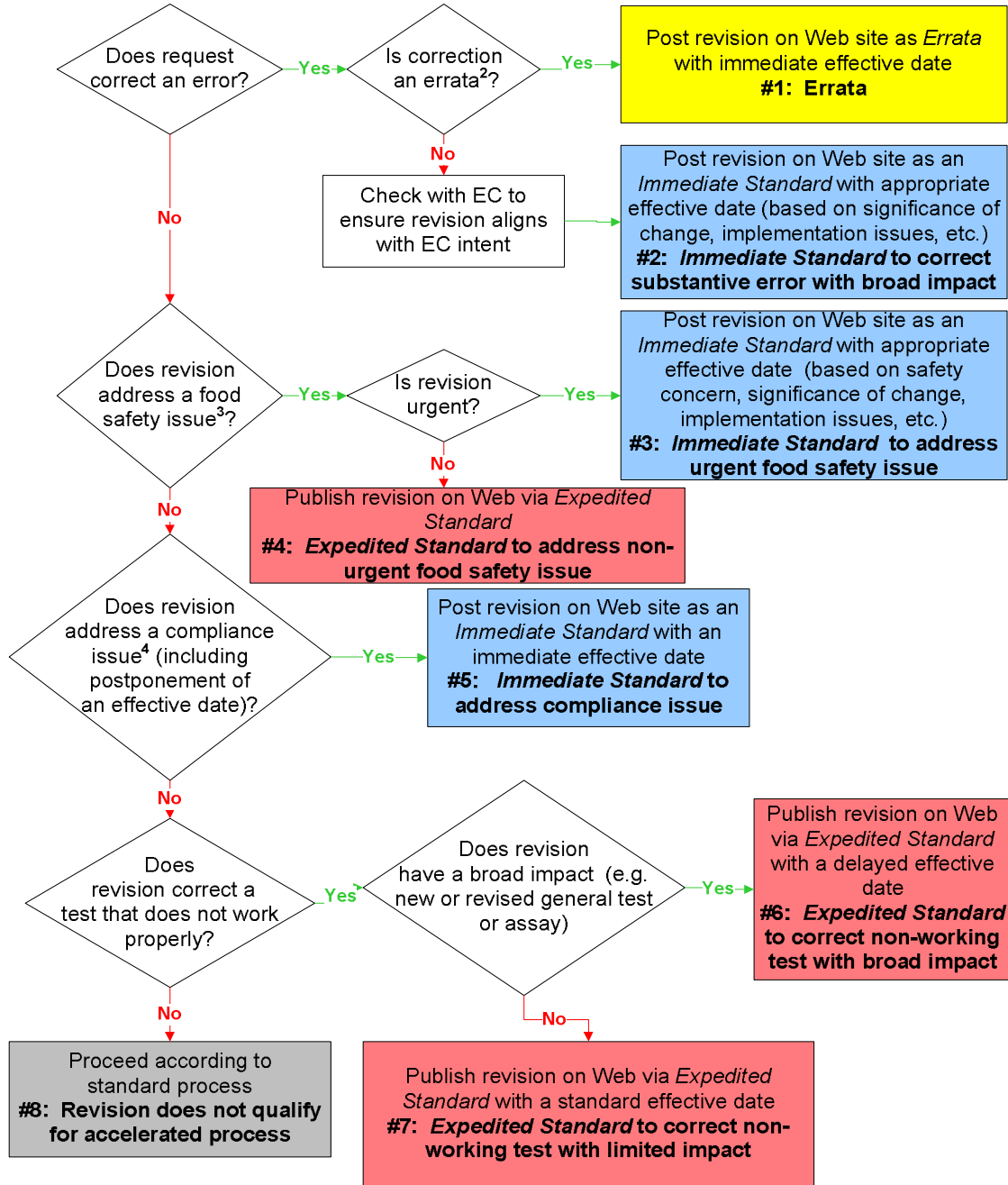
¹ "Revisions to the *Food Chemicals Codex*" include new monographs and general tests and assays as well as changes to existing monographs and general tests and assays.

² Available at <http://www.usp.org/aboutUSP/governance/policies/>.

³ See *FCC Preface* for additional information regarding *Errata*, *Expedited Standards* and *Immediate Standards*.

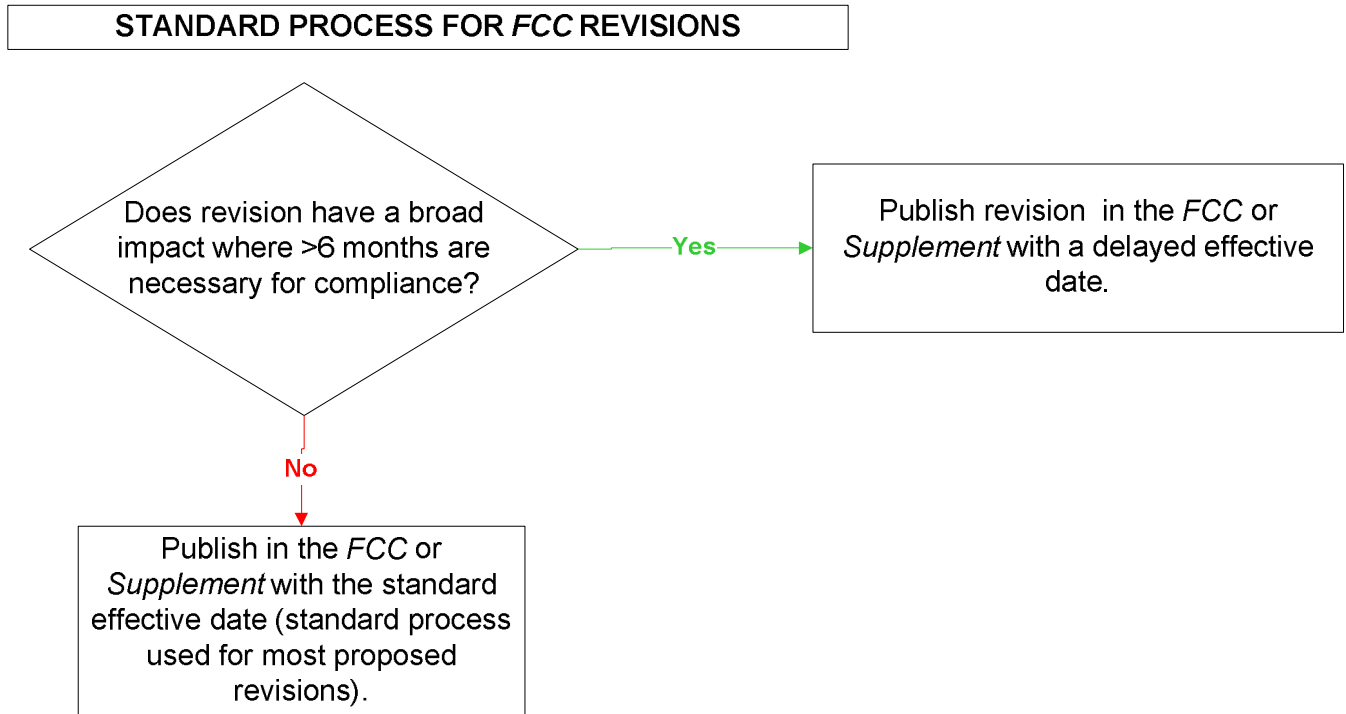
USP Guideline on Use of Accelerated Processes for Revisions to the *Food Chemicals Codex*

ACCELERATED PROCESSES FOR FCC REVISIONS DECISION TREE





USP Guideline on Use of Accelerated Processes for Revisions to the *Food Chemicals Codex*





USP Guideline on Use of Accelerated Processes for Revisions to the *Food Chemicals Codex*

Footnotes for Decision Tree

1. General

- a. Revisions to the *FCC* (whether new monographs or general test or assay or changes to existing monographs or general chapters) generally are made through the Standard Revision Process unless the revision falls into one of the categories listed in the Accelerated Revision Processes Decision Tree.
- b. *Immediate Standards* generally are posted on the USP Web site at the end of every other month, and will be effective on the first day of the second month following the posting, unless otherwise specified. (Prior to August 2012, *Immediate Standards* could be posted each month.) However, *Immediate Standards* that address an urgent food safety issue, as described in Paragraph 3 below, may be posted at any time. These *Immediate Standards* and those that address a compliance issue, as described in Paragraph 4 below, may be effective immediately.

2. Correction of errors

- a. An *Erratum/Errata* is content erroneously published in a USP publication that does not accurately reflect the intended official requirements as approved by the Council of Experts. These typically are changes that do not have a broad impact on the standards. *Errata* are not subject to public notice and comment. *Errata* are published on the USP Web site and become official on the first day of the month following publication. *Errata* are incorporated into the next available *FCC* or *Supplement*.
- b. Errors that are more substantive and do have a broad impact (such as those that impact test method instructions, solution preparations, etc. and require change control to implement) are not considered *Errata*. These errors are corrected using *Immediate Standards* with appropriate effective dates.

3. Safety-related revisions

- a. Urgent safety-related revisions are handled as *Immediate Standards*. *Expedited Standards* are used to effectuate non-urgent safety-related revisions.
- b. Prior to posting an *Immediate Standard* for a safety-related revision, USP will, as feasible and appropriate given the safety issue involved and impact of the proposed revision, obtain stakeholder input through expedited and informal processes.



USP Guideline on Use of Accelerated Processes for Revisions to the *Food Chemicals Codex*

- c. USP will consider the impact of the safety-related revision in determining the approach used to address the safety issue (speed of method development, ease of implementation in industry) and the timing of the effective date after publication.

4. Compliance related revisions

- a. Postponement of effective date: If a *FCC* standard has been published that will have the effect of putting all or a substantial part of the food industry that is required to comply with the standard out of compliance, then the use of an *Immediate Standard* that postpones the effective date of such standard to a date where compliance can reasonably be achieved is appropriate. This *Immediate Standard* will have an immediate effective date.
- b. Retraction of a standard: If a *FCC* standard has been published for a specific food ingredient for which a company that is required to comply with the standard has a legally marketed product but cannot meet the standard, then a retraction of that standard through a *Immediate Standard* with an immediate effective date is appropriate to ensure that the company is not out of compliance. Alternatively, USP may post a Notice of Intent to Revise pursuant to the Rules indicating its intent to revise the standard to address the compliance issue, and subsequently complete such revision through an *Immediate* or *Expedited Standard* or through the Standard Revision Process.
- c. Creation of a flexible monograph (inclusion of tests and procedures in a monograph that are not applicable to all manufacturers of that food ingredient): The creation of the flexible monograph must be necessary to address a compliance issue in at least one company, and the revision must not change the current monograph standards in a way that would cause a compliance issue for another company, in order to qualify for publication as an *Immediate Standard*. Examples of such revisions are the inclusion of an additional sample preparation procedure or impurity test in a monograph.



USP Guideline on Use of Accelerated Processes for Revisions to the *Food Chemicals Codex*

Revision History

G1.02-00

Document number changed and document routed through document control. No changes to Guideline content.

Version 3.1, Effective March 6, 2014

Section: Various

Change: Updated template and made minor editorial corrections.

Version 2.0, Effective August 31, 2012

Section: Footnotes for Decision Tree

Change: Specify that Immediate Standards typically are posted every other month, but may be posted at any time to address an urgent need.

Version 1.1, Effective September 1, 2011

Section: Background

Change: Updated to reflect transition to 2010-2015 cycles of the Council of Experts.

Section: Definitions and Decision Tree

Change: Revised definition of Errata and changed official date of Errata from immediately when published to the first day of the month following publication.

Version 1.0, Effective December 1, 2008

Initial version



Document Approval Certificate

This is an electronic record in the Livelink application that contains the manifestation of electronic signature(s)

UserName: Elizabeth Besteder (EDB)
Title:
Date: Tuesday, 07 July 2015, 03:24 PM Eastern Daylight Time
Meaning: Document Owner Approval

=====

UserName: Eugenia Macarthy (ECM)
Title: Project Specialist
Date: Tuesday, 14 July 2015, 11:00 AM Eastern Daylight Time
Meaning: Technical Approval 1

=====

UserName: Mario Sindaco (MYS)
Title: Director, Compendial Affairs, GAOA
Date: Tuesday, 14 July 2015, 12:08 PM Eastern Daylight Time
Meaning: Department Supervisor Approval

=====

UserName: James Schmidt (JES)
Title: Senior Auditor
Date: Tuesday, 14 July 2015, 03:45 PM Eastern Daylight Time
Meaning: QA Approval

=====