Food Chemicals Codex | FCC®

Historical Perspective on Elemental Impurity Limits in the *Food Chemicals Codex*

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Overview of Presentation

- History of Development of the Food Chemicals Codex
- Approach to Assessment of Elemental Impurities in Food Ingredients
- Advances and Changes in Elemental Impurity Limits & Methods
- Considerations for Future Revisions in Limits & Methods

Background of the Food Chemicals Codex

1958: The Food Additives Amendment to the FD&CA was passed

- Defined general quality of food chemicals required for GRAS status
- Not designed to provide specs for release or acceptance

1958: Actions by the Food Protection Committee of the National Academy of Science

- Received requests from an Industry Liaison Panel to develop a compendium with specifications
- Began the Food Chemicals Codex Project; the purpose was to be similar to the USP & NF, but for food chemicals

1961: The Food Protection Committee began to provide objective quality standards for food grade chemicals

First Edition of the Food Chemicals Codex

- Purpose of the FCC was to “define a substantial number of food-grade chemicals in terms of minimum identity and purity specifications based on the elements of safety and good manufacturing practice”
- Parts of FCC-1 were published in loose-leaf form, beginning in 1963; the final version of FCC-1 was compiled and published in 1966
- Recognition that “if the FCC is to function effectively as an authoritative book of standards for food-grade chemicals, provision for its continuous revision under appropriate sponsorship and supervision is highly essential”
- A second five-year grant was obtained to continue work on future revisions

Timeline of FCC Editions

Edition #	Eff. Date	# Monographs		Edition #	Eff. Date	# Monographs
1	1966	512		8	2012	>1100
2	1972	639		9	2014	>1200
3	1981	776		10	2016	>1200
4	1996	967		11	2018	>1200
5	2004	1077		12	2020	1255
6	2008	>1000		13	2022	1264
7	2010	>1100				

2006: Change in Ownership of the FCC

- USP acquired FCC from the National Academy of Science in 2006 and assumed responsibility for the ongoing development and publication of the FCC
- USP formed the Food Ingredients Expert Committee (FIEC), responsible for approving all new and revised FCC standards
- FIEC includes liaisons from government agencies in the US and other countries, as well as members from various countries & affiliations
- FCC-6 (2008) was published under USP ownership, and publication schedule established (new edition + 3 supplements every 2 years)

Limits of Elemental Impurities in FCC - 1

Quote from the Preface of the First Edition of FCC (1966):

"It will be the policy of the Food Chemicals Codex to set maximum limits for trace impurities wherever they are deemed to be important for a particular chemical, and they shall be set at levels consistent with safety and good manufacturing practice. **The maximum limits for heavy metals shall be 40 ppm, for lead 10 ppm, and for arsenic 3 ppm**, except in instances where higher levels cannot be avoided [under conditions of gmp]. Where a heavy metals limit of 10 ppm can be established, a separate limit for lead need not be specified."

Approach to Limits in Early FCC Editions

Heavy Metals Test:

General wet chemical test for metals colored by the sulfide ion, in a visual comparison with a Lead control standard. Nine metals are detected: Ag, As, Bi, Cd, Cu, Hg, Pb, Sb, and Sn.

FCC-2 (1972):

- Specific attention placed on the limits of heavy metal impurities
- Participation in revising and developing specifications was noted to include individual food processors & manufacturers, as well as several trade associations and foundations

Advances in Elemental Impurity Analyses

FCC-3 (1981):

- Consideration given to more specific analytical methods, such as atomic absorption (AA)

FCC-4 (1996):

- Heavy metals limits revised with input from various sources
- Significant advances included in analysis for lead, such as Flame AA and Graphite Furnace AA
- Discussion over concerns of the ability of all labs using the FCC to afford more advanced instrumentation (e.g., AA)

Updates in Lead & Heavy Metal Limits Policy

FCC-5 (2004):

- Significant revision: Removed the Heavy Metals (as Pb) specifications and replaced with specifications for relevant heavy metals in most monographs
- Arsenic specifications were removed from monographs that were “unnecessarily burdened with them”
- Considerable advances made in both analytical instrumentation and sample preparation methods for elemental impurities testing in different types of food ingredients

Current FCC Policy on Elemental Impurity Specs

- It is FCC policy to include specifications for individual elemental impurities of concern, as opposed to generic heavy metals specifications
- The Heavy Metals Limit Test is no longer listed in the FCC Appendix IIIB for Chemical Tests and Determinations – Limit Tests
- In the few cases where monographs still contain a Heavy Metals specification (e.g., NaCl, KCl, Activated Carbon), the method is written in the monograph

Monograph Examples: Lecithin & Sodium Bicarbonate

	LECITHIN – Impurity Limits (ppm or mg/kg)						SODIUM BICARBONATE - Impurity Limits (ppm or mg/kg)				
	FCC-1	**FCC-2**	**FCC-3**	**FCC-4**	**FCC-5 to current**		**FCC-1**	**FCC-2**	**FCC-3**	**FCC-4**	**FCC-5 to current**
As	3	3	3	--	--		3	3	3	--	--
HM	40	40	40	20	--		5	5	5	5	--
Pb	10	10	10	10	1		--	--	--	--	2

Monograph Examples: Phosphoric Acid & Sodium Chloride

	PHOSPHORIC ACID – Impurity Limits (ppm or mg/kg)					SODIUM CHLORIDE - Impurity Limits (ppm or mg/kg)				
	FCC-1	**FCC-2**	**FCC-3**	**FCC-4**	**FCC-5 to current**	**FCC-1**	**FCC-2**	**FCC-3**	**FCC-4**	**FCC-5 to current**
As	3	3	3	3	3	3	3	1	1	1
HM	10	10	10	5	--	5	5	4	2	2
Pb	--	--	--	--	3	--	--	--	--	--
Cd	--	--	--	--	3	--	--	--	--	--

Elemental Impurity Limits: Continued Focus

- Ongoing efforts to reduce impurity limits where possible, in new monographs and in monographs under other revisions
- Workshops have been held at USP to consider elemental impurities in pharmaceutical and food monographs
- USP laboratory staff continues to promote advancements in analytical methods and instrumentation for analysis of low levels of elemental impurities

FCC vs. USP/NF: Setting Monograph Limits

- Alignment between these compendia can be considered, but is not always the best approach
- Considerations for limits for elemental impurities must include:
  - Current knowledge of the toxicity of the impurity
  - Volume consumed of the final product (food or pharmaceutical)
  - Bioavailability of impurities based on mode of intake
    - Ingestion
    - Injection
    - Inhalation
    - Absorption

Limits in FCC Monographs: Economic Considerations

- Laboratory costs for testing according to FCC methods
  - Instrumentation, reagents, time, qualified technicians
- Cost of raw materials for food ingredients
  - Inorganic or mined substances (impurity profiles can depend on geographic regions, with varying availability and costs)
- Effectiveness and cost of various methods of purification
- Cost consideration of both acquisition and purification of food ingredients and their raw materials

Summary

- Elemental impurities have been of interest and concern in setting standards since the beginning of the food laws in the US, and the subsequent development of the FCC
- Input from stakeholders is critical for realistic information in setting standards and specifications
- Advancements in analytical methods and instrumentation continue to play a key role in reduction of elemental impurity limits
- Efforts to reduce the limits of elemental impurities in FCC monographs continues to be an ongoing process and is of importance to ensure safe foods

Thank you