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
• 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

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<th>Edition #</th>
<th>Eff. Date</th>
<th># Monographs</th>
<th>Edition #</th>
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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)

“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.”
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)
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

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<tr>
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<th>LECITHIN – Impurity Limits (ppm or mg/kg)</th>
<th>SODIUM BICARBONATE - Impurity Limits (ppm or mg/kg)</th>
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SAFEGUARDING THE INTEGRITY OF THE FOOD SUPPLY
### Monograph Examples: Phosphoric Acid & Sodium Chloride

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<tr>
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<th>PHOSPHORIC ACID – Impurity Limits (ppm or mg/kg)</th>
<th>SODIUM CHLORIDE - Impurity Limits (ppm or mg/kg)</th>
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<td>Cd</td>
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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
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