



**Elemental Impurities in Food Ingredients  
Importance and Key Role Standards Play  
in Setting Limits**

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# Elemental Impurities in Food Ingredients – Pathways to Reduction

Thanks to USP for the Opportunity To Present

Thanks to All Attending for Participating

Build an Appreciation for the Role of  
**FOODS CHEMICALS CODEX**  
in minimizing risks

# Elemental Impurities in Food Ingredients – Pathways to Reduction

## STANDARDS

- Taxes might be the Price We Pay for Civilization
- Standards are the Bolsters for an Orderly Civilization
- Standards are the Guidance to Assure Civilization (or portions thereof) Operate Smoothly.
- Standards build trust (USP verified, meets FCC specifications).
- Implicit also is that “Standard Setters” have expertise/knowledge.

# Elemental Impurities in Food Ingredients – Pathways to Reducing Levels

## Standards Can Last a Long Time

What sets some of the limits on space vehicles?

# Elemental Impurities in Food Ingredients – Pathways to Reducing Levels

## Standards Can Last a Long Time

From Horses to Space Travel

The Roman Standard for Chariot Width

Chariots to Trains

Trains to Tunnel Sizes

Tunnel Sizes to Maximum Space Vehicle Dimension(s)

# Elemental Impurities in Food Ingredients – Pathways to Reducing Levels

- Standards are **published documents**
  - Establish performance requirements
  - Identity specification and procedure
  - Testing specifications and procedures
  - Maximize the reliability of products, materials, and services
  - Ensure compatibility with other products
  - **Safeguard consumer safety**
  - Simplify product development and increase speed to market.

# Elemental Impurities in Food Ingredients – Pathways to Reduction

Publicly Set Standards  
(Often Voluntary)

A Long Tradition in the United States

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A good safety record, promoted by a voluntary standard, benefits an entire industry by enhancing consumer confidence about the safety of the market, so competitors cooperate to develop and continually improve standards.

Voluntary standards are an important contribution to society.

Consumer Products Safety Commission

<https://www.cpsc.gov/About-CPSC/Consumer-Ombudsman/Voluntary-Standards-Development-FAQ-for-Consumers#:~:text=A%20good%20safety%20record%2C%20promoted%20by%20a%20voluntary,Voluntary%20standards%20are%20an%20important%20contribution%20to%20society>



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National Technology Transfer and Advancements Act of 1995.

Office of Management and Budget Circular of 2016\*

❖ [https://www.nist.gov/system/files/revised\\_circular\\_a-119\\_as\\_of\\_01-22-2016.pdf](https://www.nist.gov/system/files/revised_circular_a-119_as_of_01-22-2016.pdf)

# Elemental Impurities in Food Ingredients – Pathways to Reducing Levels

Standards for Pharma >200 years ago

Standards for Food Additives and Ingredients ~60 years ago.

Food is very commonplace

- Humans need food (Nearly every day in significant quantity)
- Food Quality Accepted
  - Hunter Gathers
  - Farmers
  - Gardeners

# Elemental Impurities in Food Ingredients – Pathways to Reducing Levels

## Food is very commonplace

- Humans need food (Nearly every day in significant quantity)
- Food Processing and Handling Outside the Home Necessitates Safety and Quality Standards
- 1958 Amendment to Federal Food, Drug, and Cosmetics Act (aka the “Delany clause”)
  - Cancer causing concerns
  - GRAS concept

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- Regulators and Industry encouraged standardization
  - GRAS concept deemed not sufficiently specific
- FCC was “birthed” in 1961.
  - First edition published in 1963 to 1966 (Bound book in 1966).
  - Elemental impurities
    - Sufficient concern for inclusion
    - Warranted a special paragraph in the 3<sup>rd</sup> Edition of the FCC
- Strong encouragement by the FDA and other governments

# Elemental Impurities in Food Ingredients – Pathways to Reducing Levels

## IMPACT OF THE FCC

Remove Barriers to Trade

Reducing the Risk of Harm

Reducing Risk of Fraud  
Economic Harm  
Health Harm

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## Standards Operating in the Foods Arena

- USP-FCC-Monographs, Methods, Reference Standards
- AOAC-Methods
- ASTM-Packaging Standards (Specifications, Methods, Reference Standards)
- ISO
- Others: AACC, AOCS etc.

**Thank you**

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