# Industry perspectives on the role of global harmonization on food specifications

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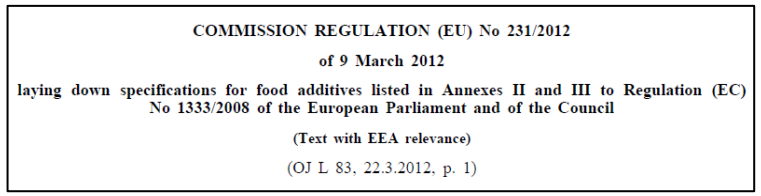
# Conflict of interest statement

I am a full-time employee of Abbott Nutrition

The views and opinions expressed in this presentation are those of myself and do not necessarily reflect the position of Abbott Nutrition

# Why does industry use specifications?

Referencing recognized specifications provides confidence that an ingredient is safe under approved conditions of use



COMMISSION REGULATION (EU) No 231/2012

of 9 March 2012

laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

(Text with EEA relevance)

(OJ L 83, 22.3.2012, p. 1)

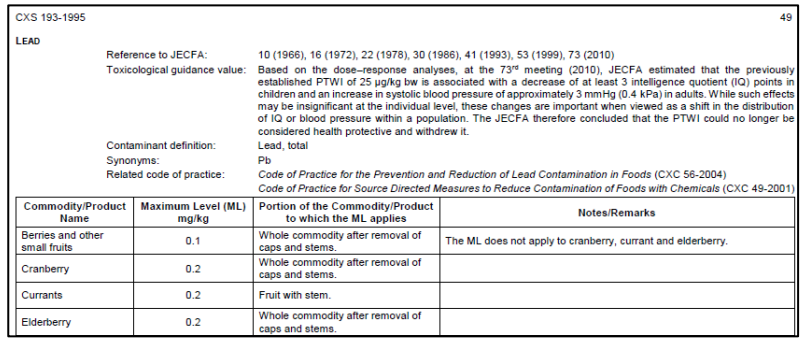
Food Chemicals Codex | FCC

Joint FAO/WHO Expert Committee on Food Additives - JECFA

JECFA 50TH ANNIVERSARY 1956 - 2006

World Health Organization

Food and Agriculture Organization of the United Nations



CXS 193-1995 49

LEAD

Reference to JECFA: 10 (1966), 16 (1972), 22 (1978), 30 (1986), 41 (1993), 53 (1999), 73 (2010)

Toxicological guidance value: Based on the dose–response analyses, at the 73rd meeting (2010), JECFA estimated that the previously established PTWI of 25 µg/kg bw is associated with a decrease of at least 3 intelligence quotient (IQ) points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults. While such effects may be insignificant at the individual level, these changes are important when viewed as a shift in the distribution of IQ or blood pressure within a population. The JECFA therefore concluded that the PTWI could no longer be considered health protective and withdrew it.

Contaminant definition: Lead, total

Synonyms: Pb

Related code of practice: *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXC 56-2004); *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals* (CXC 49-2001)

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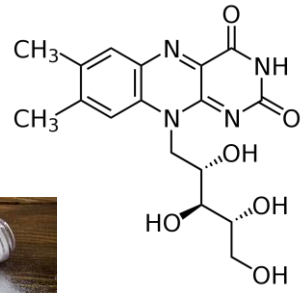
# What do specifications define?

## A specification defines what an ingredient is

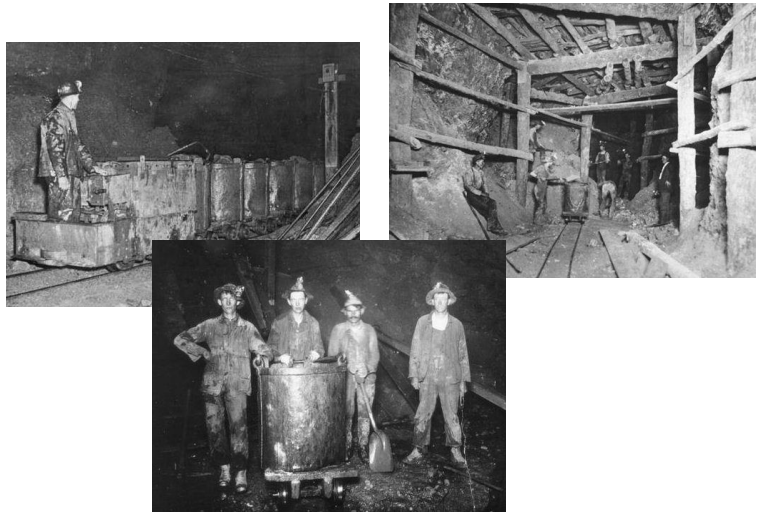

## What should be there

- The substance you are intending to add
- Other “good for you” components

## What shouldn’t be there

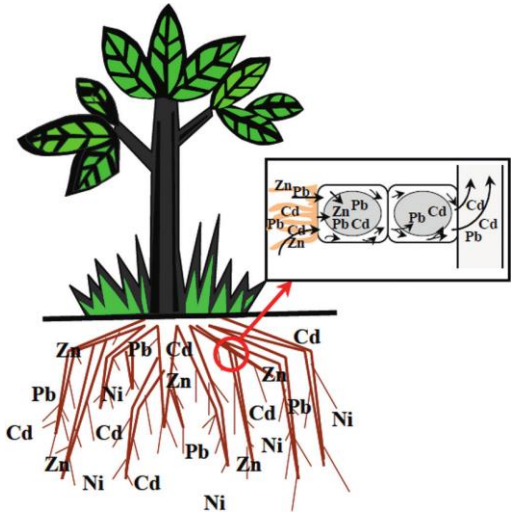
- Substances that may be present, but you are trying to avoid or minimize

# Specifications help control contaminants inherent in food

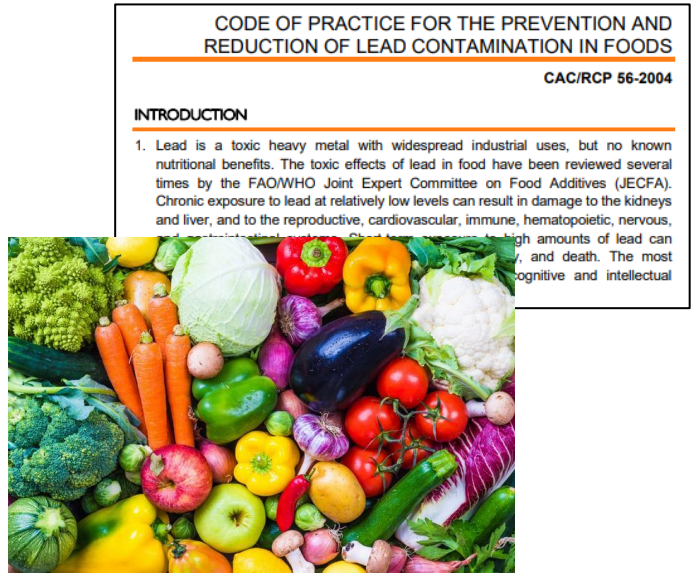


Mean soil concentrations of lead in the US: 25.8 ppm

2007 USGS Survey
Smith et al., 2013.
https://pubs.usgs.gov/ds/801/




Plants (including crops) absorb lead from soil along with desirable minerals (zinc, copper)



CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF LEAD CONTAMINATION IN FOODS

CAC/RCP 56-2004

INTRODUCTION

1. Lead is a toxic heavy metal with widespread industrial uses, but no known nutritional benefits. The toxic effects of lead in food have been reviewed several times by the FAO/WHO Joint Expert Committee on Food Additives (JECFA). Chronic exposure to lead at relatively low levels can result in damage to the kidneys and liver, and to the reproductive, cardiovascular, immune, hematopoietic, nervous,

...igh amounts of lead can ..., and death. The most ...ognitive and intellectual

All foods have inherent amounts of unavoidable lead

# Heavy metals are not readily-avoidable substances

## Readily-avoidable substances

Substances intentionally added to foods and other products for a technological or functional purpose

- Food additives: Emulsifiers, stabilizers, antioxidants
- Manufacturing essential substances: Sanitizers, cleansers, lubricants

## Not readily-avoidable substances

Substances present in the environment or that are produced through standard food manufacturing processes

- Environmentally-present: heavy metals, mycotoxins
- Process-formed: 3-MCPD, acrylamide

Rodricks et al., 2020. Food Constituents and Contaminants.
ISBN# 9781119438922

# Risk management measures are substance-specific

## Readily-Avoidable

- Substances are intentionally added, and can be intentionally removed
- Risk management occurs through:
  - Adding less Establishing maximum allowable levels in foods (when necessary), or
  - Not adding it at all Authorizing (and de-authorizing) use in specific food categories, and

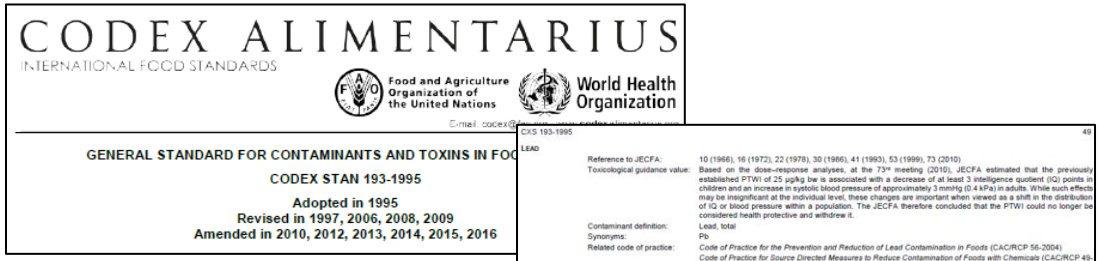
## Not Readily-Avoidable

- Substances are unavoidable and unintentionally present
- Exposure can usually be reduced, but never eliminated
- Mitigation often has secondary effects that must be considered
- Risk management includes setting regulatory limits/specifications

# Setting specifications for heavy metals in food

The Codex Committee on Contaminants in Foods (CCCF) has criteria to guide development of contaminant limits:

1. Limits should be set to protect the consumer
2. Limits should consider what is achievable
3. Validated analytical methods should be available



CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations
World Health Organization

GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOO

CODEX STAN 193-1995

Adopted in 1995
Revised in 1997, 2006, 2008, 2009
Amended in 2010, 2012, 2013, 2014, 2015, 2016



CXS 193-1995 49

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# Protecting the consumer: Establishing safe levels

Food risk assessment includes evaluating the hazard associate with a substance in the context of the amount of exposure

This information is used to establish an acceptable daily intake, which is a conservative estimate of the amount of a substance that could be consumed every day over the course of a lifetime without appreciable risk of adverse effects

# Heavy metal safety limits

There is a safe level of exposure to heavy metals, below which there would be no appreciable risk

However, there is a lack of consensus about what that level is, and whether we have enough data to be able to determine that level

The amount of heavy metal exposure from all sources (food, water, air, other environmental sources) indicates there is risk, and thus reducing exposure from food may help reduce overall exposure, even if it is not the most significant source of exposure

# Considering achievability and secondary effects

Heavy metal specifications consider what can be achieved, and how the limits will drive reductions

Establishing levels are not achievable could lead to:

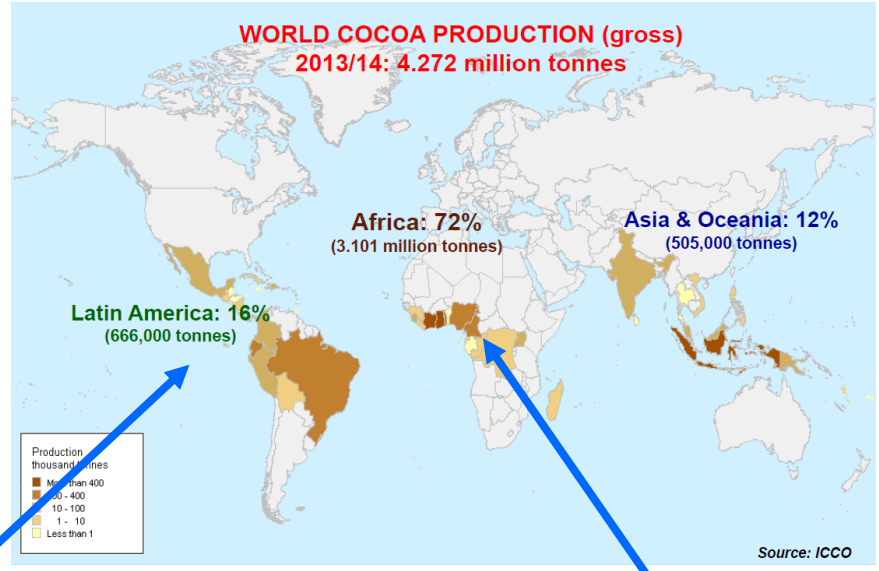
- Eliminating access to foods and/or increasing cost
- Consumers making decisions that have nutritional implications (e.g. avoiding fish or specific vegetables)

| Food Category | N + / N | Lead concentration (mg/kg) | | | | | |
|---|---|---|---|---|---|---|---|
| | | Mean | Median | P95TH | P97.5TH | Min | Max |
| Eggs and eggs products | 790/2,143 | 0.19 | 0.02 | 0,58 | 1.24 | 0.0001 | 27.7 |
| Nuts and oilseeds | 1129/3,857 | 0.02 | 0.01 | 0.06 | 0.10 | 0.0001 | 1.41 |
| Cereal flours and starch | 1,030/2,406 | 0.02 | 0.01 | 0.05 | 0.06 | 0.0004 | 0.30 |

Codex Discussion Paper on Maximum Levels for Lead: May 2019

$N^+/N$ = positive samples/total samples

# Specifications can be beneficial in the absence of a safety concern




Higher naturally-occurring cadmium due to soil with high levels of volcanic ash

Lower naturally-occurring cadmium in soil, and therefore lower levels in cocoa

Cadmium is inherent in cocoa, but JECFA determined that the amount of cadmium exposure from cocoa is insignificant and therefore not a safety concern

Codex is still establishing limits for cadmium in cocoa to facilitate global trade

# Validated methods should be available

Limits should only be set if appropriate methods are available to detect that amount of a substance in the food of interest.

This can be challenging for analyzing food because of:

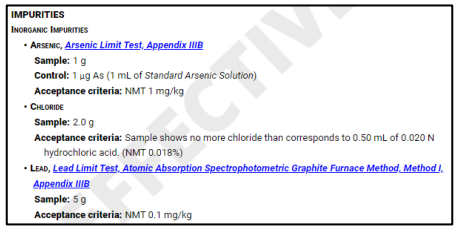
- Limited availability of methods Speciation of metals requires specialized instrumentation that is currently not broadly available
- Food matrix complexity Some foods, such as those high in minerals can be challenging to analyze
- More uncertainty near the LOQ If limits are set at/near the LOQ, there will be more variability in results and more false positives/negatives

# Applications of specifications

## Monographs

Set for broadly used food substances like additives, vitamins, and minerals

Food Chemicals Codex | FCC



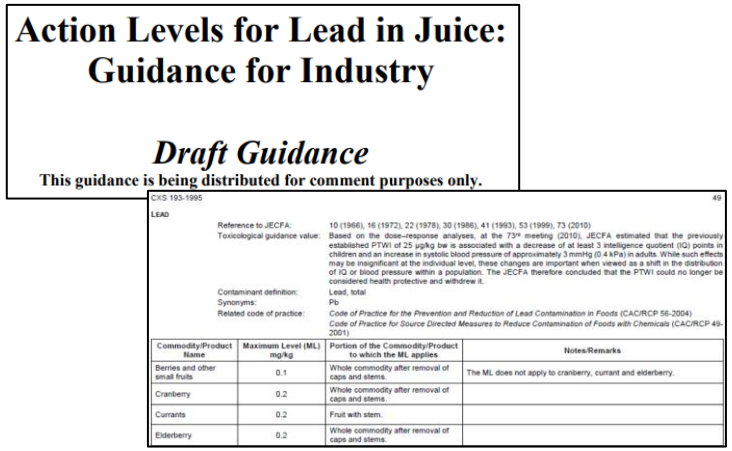
IMPURITIES

INORGANIC IMPURITIES

- ARSENIC, *Arsenic Limit Test, Appendix IIIB*
  **Sample:** 1 g
  **Control:** 1 µg As (1 mL of *Standard Arsenic Solution*)
  **Acceptance criteria:** NMT 1 mg/kg
- CHLORIDE
  **Sample:** 2.0 g
  **Acceptance criteria:** Sample shows no more chloride than corresponds to 0.50 mL of 0.020 N hydrochloric acid. (NMT 0.018%)
- LEAD, *Lead Limit Test, Atomic Absorption Spectrophotometric Graphite Furnace Method, Method I, Appendix IIIB*
  **Sample:** 5 g
  **Acceptance criteria:** NMT 0.1 mg/kg

## Food limits

Established in commodities and finished products by regulatory agencies and company internal controls



**Action Levels for Lead in Juice: Guidance for Industry**

***Draft Guidance***

**This guidance is being distributed for comment purposes only.**

CXS 193-1995 49

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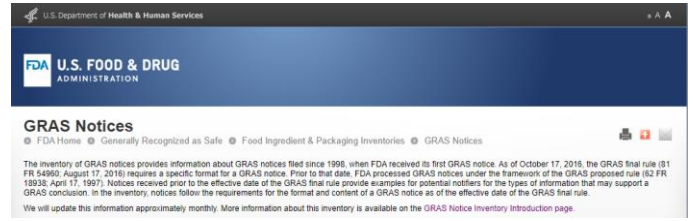
## Novel foods

Specifications are set and reviewed during approval of new food ingredients



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

GRAS Notices

FDA Home · Generally Recognized as Safe · Food Ingredient & Packaging Inventories · GRAS Notices

The inventory of GRAS notices provides information about GRAS notices filed since 1998, when FDA received its first GRAS notice. As of October 17, 2016, the GRAS final rule (81 FR 54960; August 17, 2016) requires a specific format for a GRAS notice. Prior to that date, FDA processed GRAS notices under the framework of the GRAS proposed rule (62 FR 18938; April 17, 1997). Notices received prior to the effective date of the GRAS final rule provide examples for potential notifiers for the types of information that may support a GRAS conclusion. In the inventory, notices follow the requirements for the format and content of a GRAS notice as of the effective date of the GRAS final rule.

We will update this information approximately monthly. More information about this inventory is available on the GRAS Notice Inventory Introduction page.

| Parameter | Unit | Specification | Method[1] |
|---|---|---|---|
| Lead | mg/kg | NMT 1.0 | ICP MS Heavy Metals AOAC 2015.01 Mod<2232 |
| Arsenic | mg/kg | NMT 1.0 | |

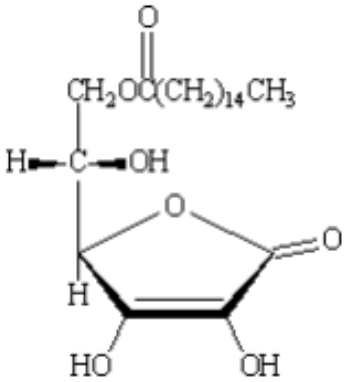
# Specifications use the same principles regardless of application

Defining and reviewing contaminant specifications follow a similar process, regardless of application:

- Is the source of the food a likely contributor of a specific heavy metal?
- Does the production process increase or decrease the concentration of the heavy metal?
- What does the data show is technically achievable?
- Do the achievable levels present a safety concern?

# Monograph example: Ascorbyl palmitate

| | FCC | USP | JECFA | EU | China GB |
|---|---|---|---|---|---|
| Purity | ≥ 95.0% | 95.0 – 100.5% | ≥ 95.0% | ≥ 98.0% | ≥ 95.0% |
| Lead | ≤ 2 ppm | - | ≤ 2 ppm | ≤ 2 ppm | ≤ 2 ppm |
| Cadmium | - | - | - | - | - |
| Arsenic | - | - | - | ≤ 3 ppm | ≤ 3 ppm |
| Mercury | - | - | - | ≤ 1 ppm | - |




Multiple agencies have established specifications for common food additives, such as ascorbyl palmitate (INS 304)

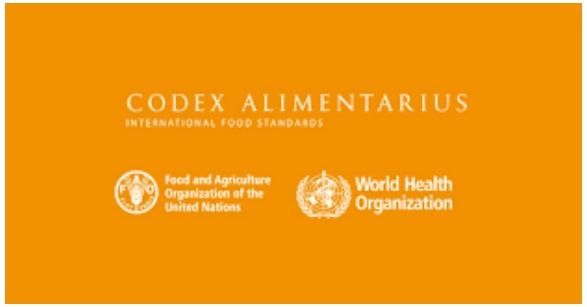
# Food limits example: Codex Alimentarius

Codex Alimentarius has established maximum levels (MLs) for forty different food categories including commodities and finished goods

The Codex process is very similar to other approaches such as the US FDA Closer to Zero program

| Commodity/Product Name | Maximum Level (mg/kg) |
|---|---|
| Milk | 0.02 |
| Fish | 0.3 |
| Table olives | 0.4 |
| Cereal grains | 0.2 |
| Pulses | 0.1 |
| Cranberries | 0.2 |
| Wine | 0.1 |
| Infant formula | 0.01 |
| Grape juice | 0.04 |
| Jams and jellies | 0.4 |
| Canned vegetables | 0.1 |

Codex Standard CXS 193-1995



# Novel food example: US FDA GRAS

A critical element to the safety evaluation of novel foods, such as through the US FDA GRAS Notification program, is a review of the specifications of the ingredient

GRN 967: Soluble egg-white protein

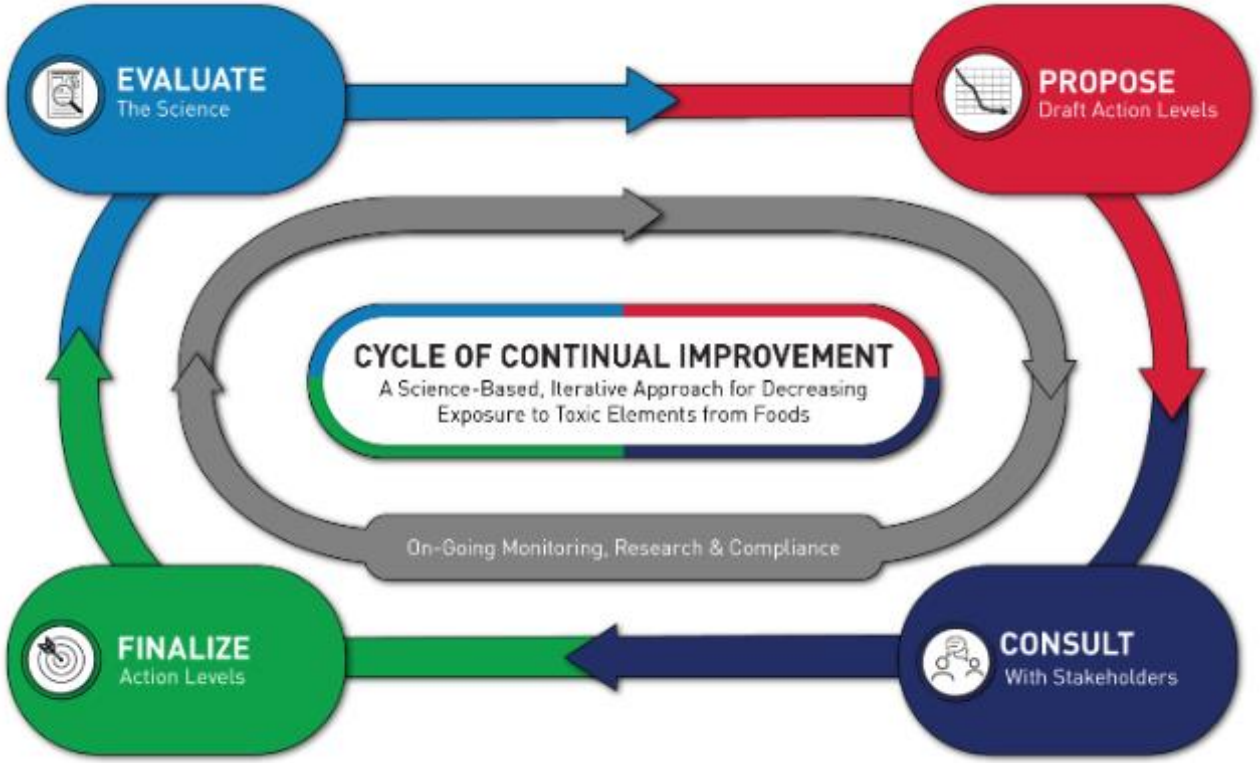
| Chemical Properties (in powder as is) | Specification |
|---|---|
| Protein | > 75% |
| Moisture | Maximum 10.0% |
| Carbohydrate | Maximum 20% |
| Ash | Maximum 2.0% |
| Fat by Acid Hydrolysis | < 0.1% |
| Hg | < 1 ppm |
| Pb | < 1 ppm |
| As | < 1 ppm |
| Cd | < 1 ppm |

| Parameter | Specification |
|---|---|
| ***Proximate analysis*** | |
| Moisture (%) | <7 |
| Protein (%)[a] | >80 |
| Fat (%) | 3 to 5 |
| Ash (%) | <8 |
| Carbohydrate (%) | <10 |
| ***Microbiological*** | |
| Aerobic plate count (CFU/g) | <100,000 |
| *Listeria* spp. | Negative |
| *Salmonella* spp. | Negative |
| *Escherichia coli* | Negative |
| ***Heavy metals*** | |
| Arsenic (ppm) | ≤0.05 |
| Cadmium (ppm) | ≤0.05 |
| Lead (ppm) | ≤0.05 |
| Mercury (ppm) | ≤0.025 |

| der as is) | Specification |
|---|---|
| | < 10000 CFU/g |
| | < 100 CFU/g |
| | Not Detected / 25g |
| | Not Detected / 25g |
| | ≤ 30 CFU/g |

GRN 684: Mung bean protein isolate

# Food companies are a stakeholder in Closer to Zero




Many of the elements emphasized in the US FDA Closer to Zero program are the same as those discussed in this presentation

# Thank you

Paul Hanlon

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