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.
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)

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
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)

<table>
<thead>
<tr>
<th>Food Category</th>
<th>N+/N</th>
<th>Lead concentration (mg/kg)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>Median</td>
<td>(P_{95}^{TH})</td>
<td>(P_{97.5}^{TH})</td>
<td>Min</td>
<td>Max</td>
</tr>
<tr>
<td>Eggs and eggs products</td>
<td>790/2,143</td>
<td>0.19</td>
<td>0.02</td>
<td>0.58</td>
<td>1.24</td>
<td>0.0001</td>
<td>27.7</td>
</tr>
<tr>
<td>Nuts and oilseeds</td>
<td>1129/3,857</td>
<td>0.02</td>
<td>0.01</td>
<td>0.06</td>
<td>0.10</td>
<td>0.0001</td>
<td>1.41</td>
</tr>
<tr>
<td>Cereal flours and starch</td>
<td>1,030/2,406</td>
<td>0.02</td>
<td>0.01</td>
<td>0.05</td>
<td>0.06</td>
<td>0.0004</td>
<td>0.30</td>
</tr>
</tbody>
</table>

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

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

Novel foods
Specifications are set and reviewed during approval of new food ingredients
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

<table>
<thead>
<tr>
<th></th>
<th>FCC</th>
<th>USP</th>
<th>JECFA</th>
<th>EU</th>
<th>China GB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purity</td>
<td>≥ 95.0%</td>
<td>95.0 – 100.5%</td>
<td>≥ 95.0%</td>
<td>≥ 98.0%</td>
<td>≥ 95.0%</td>
</tr>
<tr>
<td>Lead</td>
<td>≤ 2 ppm</td>
<td>-</td>
<td>≤ 2 ppm</td>
<td>≤ 2 ppm</td>
<td>≤ 2 ppm</td>
</tr>
<tr>
<td>Cadmium</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Arsenic</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>≤ 3 ppm</td>
<td>≤ 3 ppm</td>
</tr>
<tr>
<td>Mercury</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>≤ 1 ppm</td>
<td>-</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Commodity/Product Name</th>
<th>Maximum Level (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk</td>
<td>0.02</td>
</tr>
<tr>
<td>Fish</td>
<td>0.3</td>
</tr>
<tr>
<td>Table olives</td>
<td>0.4</td>
</tr>
<tr>
<td>Cereal grains</td>
<td>0.2</td>
</tr>
<tr>
<td>Pulses</td>
<td>0.1</td>
</tr>
<tr>
<td>Cranberries</td>
<td>0.2</td>
</tr>
<tr>
<td>Wine</td>
<td>0.1</td>
</tr>
<tr>
<td>Infant formula</td>
<td>0.01</td>
</tr>
<tr>
<td>Grape juice</td>
<td>0.04</td>
</tr>
<tr>
<td>Jams and jellies</td>
<td>0.4</td>
</tr>
<tr>
<td>Canned vegetables</td>
<td>0.1</td>
</tr>
</tbody>
</table>

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.
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

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