U.S. FOOD & DRUG ADMINISTRATION

Is Global Harmonization of Food Standards Possible for Arsenic, Cadmium, and Lead?

JIFSAN-CFS3 Annual Symposium: Understanding the Impact of Arsenic, Cadmium, and Lead Across the Food Supply
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Disclaimer

Views expressed in this presentation are those of the author and do not necessarily reflect the views or policies of the Food and Drug Administration.

Today's talk

- Codex Alimentarius Commission
  - What it is, what it does, the Codex process
- Codex Committee on Contaminants in Foods
- Recent work on arsenic, cadmium, and lead
- Is harmonization possible?

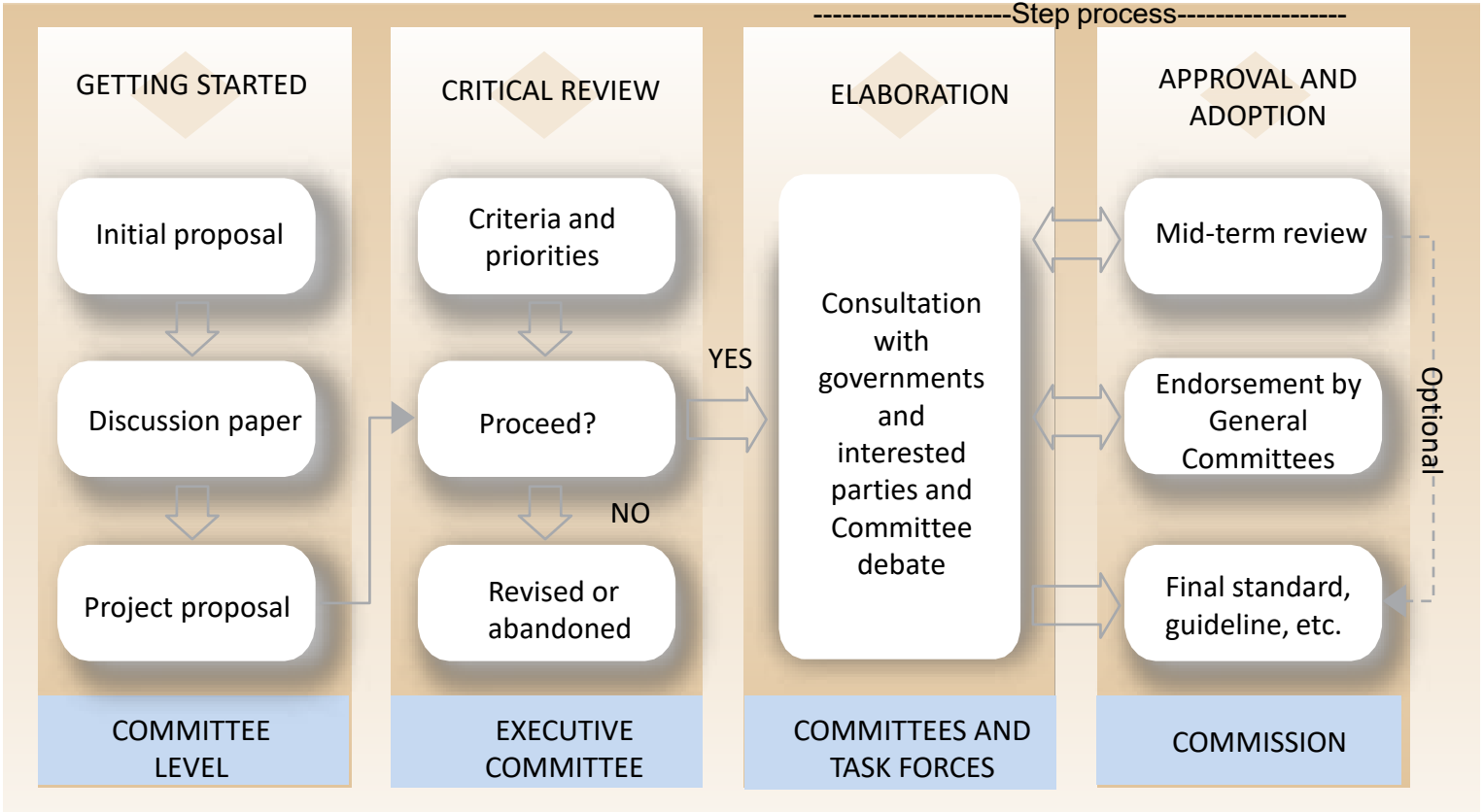
Codex Alimentarius Commission (CAC)

- Established by Food and Agriculture Organization (FAO) and World Health Organization (WHO) in 1963
- Goals
  - To protect the health of consumers
  - To ensure fair practices in the food trade
- Develops harmonized international food standards, guidelines and codes of practice for publication in the Codex Alimentarius
  - Documents and Codex information online at http://www.fao.org/fao-who-codexalimentarius/en/

Codex Committees

- CAC establishes subsidiary committees, including general and commodity committees.
  - General committees: Contaminants, Food Hygiene, Pesticide Residues, Food Additives, Food Labeling, Methods of Analysis and Sampling, Vet Drugs, General Principles, Nutrition, and Import/Export Certification
  - Commodity committees (active): Cereals/Pulses/Legumes, Fats and Oils, Spices and Culinary Herbs, Processed Fruits and Vegetables, Fresh Fruits and Vegetables
  - Coordinating committees and task forces
- U.S. Codex Office in USDA is central Codex contact point
- Delegates and alternate delegates come from FDA, USDA, EPA, and Commerce.

Codex Standards Process



Codex Step Process

Codex Committee on Contaminants in Foods (CCCF)

- FDA leads US Delegation to CCCF (alternate delegate from USDA)
- CCCF Terms of reference:
  - to establish or endorse permitted maximum levels or guideline levels for contaminants and naturally occurring toxicants in food and feed
  - to consider and elaborate standards or codes of practice for related subjects
  - to consider methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed

CCCF and JECFA

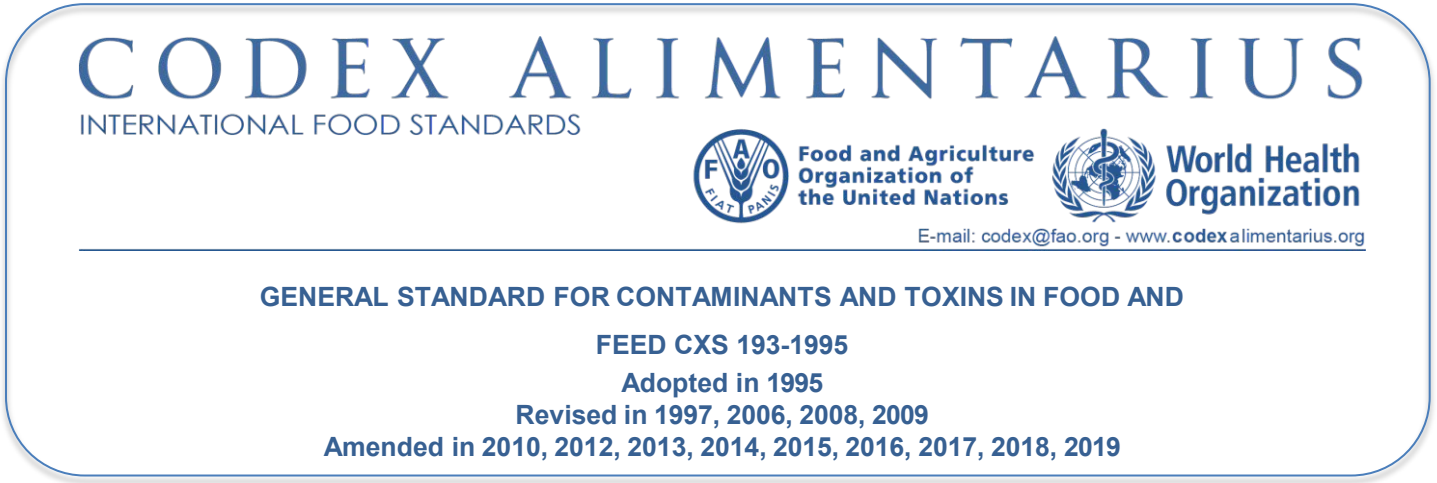
- CCCF Terms of reference (continued)
  - to prepare priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)
  - to consider other matters assigned by the Commission
- JECFA
  - International expert committee administered by FAO and WHO.
  - Performs exposure and risk assessments, provides advice.
  - Risk assessor for CCCF

CCCF Develops MLs and COPs

- CCCF standards work is codified in General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, CODEX STAN 193-1995)
  - Lists maximum levels (MLs) and guideline levels (GLs), and associated sampling plans for contaminants and natural toxicants in food and feed recommended by the CAC to be applied to commodities moving in international trade.
  - Covered contaminants include metals, mycotoxins, process contaminants, radionuclides.
  - Also includes main principles recommended in dealing with contaminants, e.g., criteria for setting MLs.
- Codes of Practice on preventing and reducing contaminants in foods, including mycotoxins, arsenic, lead, and 3-MCPD and glycidyl esters.

MLs and COPs

- The following slides will review Codex MLs and COPs for lead, cadmium, arsenic, and methylmercury from the last 10 years.
  - In addition to the listed MLs, many outdated MLs and Guideline Levels were revoked.
  - ML development is based on review of occurrence data in the WHO/GEMSFood database and consideration of risk assessments by JECFA.



Lead

Year	MLs	Code of Practice
2004		**Code of practice for the prevention and reduction of lead contamination in foods (chaired by USA)**
2011-2013	New work on revising existing MLs for lead with focus on foods important for infants and children and canned fruits and vegetables (chaired by USA).	
2014	• **Infant formula and related formulas, 0.02 → 0.01 mg/kg**	

Lead

Year	MLs	Code of Practice
2015	• **Fruit juices and nectars, ready to drink (excluding juices exclusively from berries and other small fruits and passion fruit), 0.05 mg/kg → 0.03 mg/kg** • **Juices exclusively from berries and other small fruits and passion fruit, 0.05 mg/kg** • **Canned fruits (excluding canned berries and other small fruits), 1.0 mg/kg → 0.1 mg/kg** • **Canned vegetables (excluding canned brassica, leafy, and legume vegetables), 1.0 mg/kg → 0.1 mg/kg** • **Berries and other small fruits (excluding cranberry, currant, elderberry), 0.2 mg/kg → 0.1 mg/kg** • Cranberry, currant, and elderberry, 0.2 mg/kg • **Brassica vegetables, 0.3 → 0.1 mg/kg** • **Legume vegetables, 0.2 → 0.1 mg/kg** • **Fruiting vegetables, other than fungi and mushrooms, 0.1 mg/kg → 0.05 mg/kg**	

Lead

Year	MLs	Code of Practice
2016	• Passion fruit juice/nectar, inclusion in fruit juices ML, 0.03 mg/kg • Canned berries and other small fruits, inclusion in canned fruits ML, 0.1 mg/kg • Canned leafy vegetables and canned legume vegetables, inclusion in canned vegetables ML, 0.1 mg/kg • Pickled cucumbers, 1.0 mg/kg → 0.1 mg/kg • Table olives, 1.0 → 0.4 mg/kg	
2017	• Preserved Tomatoes, 1.0 mg/kg → 0.05 mg/kg • Jams, Jellies and Marmalades, 1.0 mg/kg→ 0.4 mg/kg • Canned Chestnuts and Canned Chestnuts Puree, 1.0 mg/kg→ 0.05 mg/kg • **Pulses, 0.2 mg/kg → 0.1 mg/kg**	

Lead

Year	MLs	Code of Practice
2018	• **Grape juice, 0.05 mg/kg → 0.04 mg/kg** • Mango chutney, 1.0 g/kg → 0.4 mg/kg • Canned brassica vegetables, inclusion in canned vegetables ML, 0.1 mg/kg • **Fresh farmed mushrooms (common, shiitake, and oyster), 0.3 mg/kg** • **Salt, excluding salt from marshes, 2.0 → 1 mg/kg** • **Fat spreads and blended spreads, 0.1 mg/kg → 0.04 mg/kg** • **Edible fats and oils, 0.1 → 0.08 mg/kg** *Discussion paper for prioritizing new work on lead MLs (chaired by Brazil)*	New work approved on revision of Code of practice for the prevention and reduction of lead contamination in foods (chaired by USA)

Lead

Year	MLs	Code of Practice
2019	• **Wines (from grapes harvested after the adoption of the ML by CAC), 0.2 → 0.1 mg/kg** • **Fortified/liqueur wines (from grapes harvested after the adoption of the ML by CAC), 0.15 mg/kg** • Edible offal of cattle, 0.5 → 0.2 mg/kg • Edible offal of pig, 0.5 → 0.15 mg/kg • Edible offal of poultry, 0.5 → 0.1 mg/kg *Work on lead MLs revision complete.*	
2021		**Revised Code of practice for the prevention and reduction of lead contamination in foods adopted.**

Lead

Year	MLs	Code of Practice
2022	**Forwarded for adoption to CAC:** • **Cereal-based products for infants and young children, 0.02 mg/kg, (Step 5/8)** • **Ready to eat meals for infants and young children, 0.02 mg/kg (Step 5, allowing further evaluation of certain foods)** • **Refined sugar, corn syrup, maple syrup, honey, 0.1 mg/kg (Step 5/8)** • **Sugar-based candies, 0.1 mg/kg (Step 5/8)**	
2023	• *Fresh and dried spices and culinary herbs (scheduled)* • *Brown and raw sugars (scheduled)*	

Cadmium

Year	MLs	Code of Practice
2014	New work approved on MLs for cadmium in chocolate and cocoa-derived products (chaired by Ecuador)	
2017		New work approved on COP for prevention and reduction of cadmium in cocoa beans (chaired by Peru)
2018	• **Chocolates containing or declaring ≥ 50% to < 70% total cocoa solids (TCS), 0.8 mg/kg** • **Chocolates containing or declaring ≥ 70% TCS, 0.9 mg/kg**	
2021	• **Chocolates containing or declaring < 30% TCS, 0.3 mg/kg** • **Chocolates containing or declaring ≥30% to <50% TCS, 0.7 mg/kg**	Forwarded for adoption to CAC: • COP on cadmium in cocoa beans (Step 5)
2022	Forwarded for adoption to CAC: • **100% cocoa powder, 2.0 mg/kg (Step 5/8)**	Forwarded for adoption to CAC: • **COP on cadmium in cocoa beans (Step 8)**

Arsenic

Year	MLs	Code of Practice
2011	New work approved on MLs for arsenic in rice (chaired by Japan)	
2013		Discussion paper (chaired by China)
2014	• **Polished rice, 0.2 mg/kg inorganic arsenic (iAs)**	New work approved on Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice (chaired by Japan/China)
2015	• Husked rice, 0.35 mg/kg iAs (Step 5)	
2016	• **Husked rice, 0.35 mg/kg iAs (Step 8)**	
2017	• Existing edible fats and oils ML extended to fish oils, 0.1 mg/kg	**Code of practice for the prevention and reduction of arsenic contamination in rice adopted**

Methylmercury

Year	MLs	Code of Practice
2017	New work approved on MLs for methylmercury (MeHg) in fish (chaired by the Netherlands, New Zealand, and Canada)	
2018	• **Tuna, 1.2 mg/kg** • **Alfonsino, 1.5 mg/kg** • **Marlin, 1.7 mg/kg** • **Shark, 1.6 mg/kg**	
2022	Forwarded for adoption to CAC: • **Pink cusk-eel, 1.0 mg/kg (Step 5/8)** • **Orange roughy, 0.8 mg/kg (Step 5/8)**	

Yes, harmonization is possible

- In the last 10 years, Codex completed three new or revised toxic element related codes of practice and adopted more than 40 new or revised MLs for lead, cadmium, arsenic, and methylmercury.
- Harmonization can occur without complete agreement.
  - For example, four MeHg MLs were adopted or forwarded for adoption without US support and with EU reservations.
  - Five MLs for Cd in chocolate products were adopted or forwarded for adoption, with EU reservations.
  - An ML for As in husked rice was adopted with EU reservation.
- Further harmonization can occur as Codex MLs inform national legislation and guidance.
  - Some countries adopt Codex standards directly.
  - FDA lead in juice proposed guidance cites work in Codex.

What supports harmonization?

- Mutual interest in establishing or revising an ML
- Evidence that lack of harmonization hinders trade
- Sufficient high quality occurrence data in WHO/GEMSFood database.
- Geographically and chronologically representative data
- A transparent and well-founded analysis
- A JECFA assessment supporting risk management action
- High quality technical input from stakeholders

Is harmonization always desirable?

- Some industry stakeholders have shared that harmonization supports global trade by providing a globally enforceable standard.
- But other industry stakeholders have pointed out that a globally harmonized standard may negatively impact trade if national standards are lowered due to harmonization.
  - Example: Aflatoxin in ready to eat peanuts

Participation and Additional information

- U.S. strives to participate in each EWG in CCCF, either as a member, co-chair, or chair.
- Stakeholders with particular interests or technical expertise relevant to an agenda item can provide input on drafts to the U.S. delegation.
- Draft U.S. positions on final papers are discussed at a Public Meeting in early spring.

Additional information:

- USCO: www.usda.gov/codex
  - Delegate's Report, Public Meetings, Stakeholder information
- Codex : www.codexalimentarius.net
- U.S. CCCF Delegation contacts:
  - Lauren.Robin@fda.hhs.gov (Delegate), Eileen.Abt@fda.hhs.gov (Toxic Elements Expert), Quynh-anh.Nguyen@fda.hhs.gov (Stakeholder Outreach)
  - Alexander.Domesle@usda.gov (Alternate Delegate), Doreen.Chenmoulec@usda.gov (USCO)

Thank you for your attention

Questions?