

Key Regulatory Issues Affecting the Pasta Industry

Presentation for the National Pasta Association

Veronica Colas, Counsel

October 24, 2024

Agenda

- FDA Structure
- FDA Nutrition and Labeling Initiatives
- UPF
- Chemical Contaminants
- State Meddling
- Other Fun



FDA's Foods Program Rebuilding or Rebranding?



New Leadership

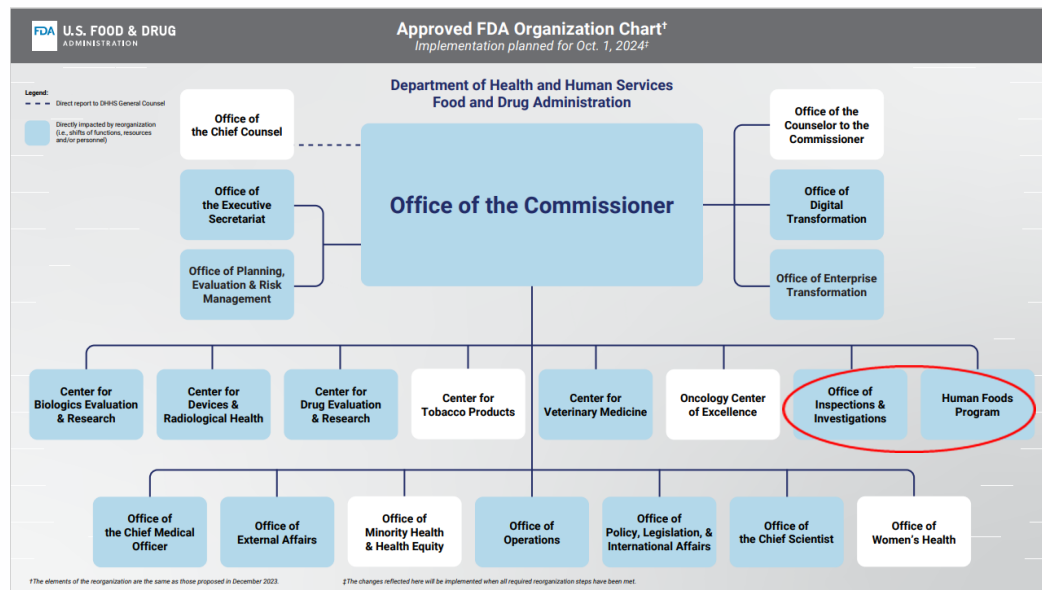
- Jim Jones, Deputy Commissioner for Human Foods
 - Reports directly to Commissioner
 - Heads the human foods program
 - Food Safety
 - Chemical Safety
 - Nutrition Activities
- 30-year tenure at EPA



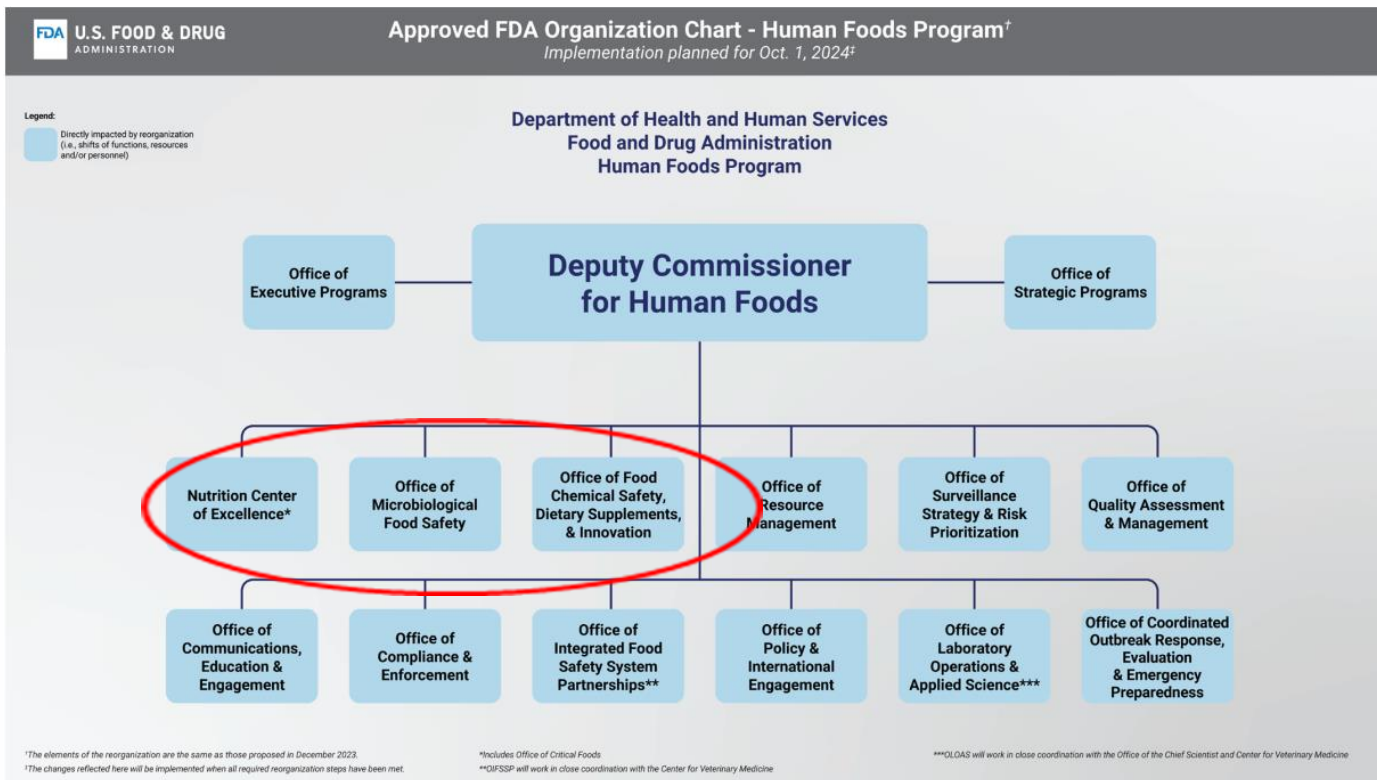
FDA Reorganization

Key changes:

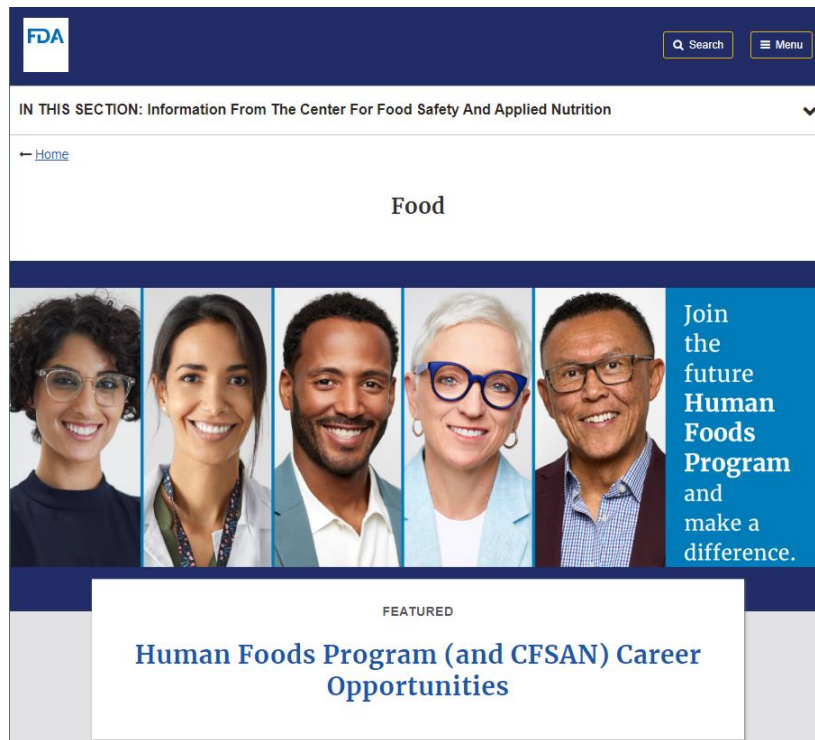
- Functions of the Center for Food Safety and Applied Nutrition, the Office of Food Policy and Response, and key functions from the Office of Regulatory Affairs (ORA) will be housed under one program
- The Office of Regulatory Affairs (ORA) is renamed the Office of Inspections and Investigations (OII)
 - Frontline of field-based inspection, investigation, and import operations



Approved HFP Org Chart



FDA Currently Hiring to Fill New Roles Created by Reorganization



The screenshot shows the FDA website's 'Food' section. At the top is the FDA logo and a navigation bar with 'Search' and 'Menu' buttons. Below the navigation bar, a section titled 'IN THIS SECTION: Information From The Center For Food Safety And Applied Nutrition' includes a 'Home' link. The main heading 'Food' is centered. A large banner features five diverse professionals and the text 'Join the future Human Foods Program and make a difference.' Below the banner, a 'FEATURED' box highlights 'Human Foods Program (and CFSAN) Career Opportunities'.

FDA

Search Menu

IN THIS SECTION: Information From The Center For Food Safety And Applied Nutrition

[Home](#)

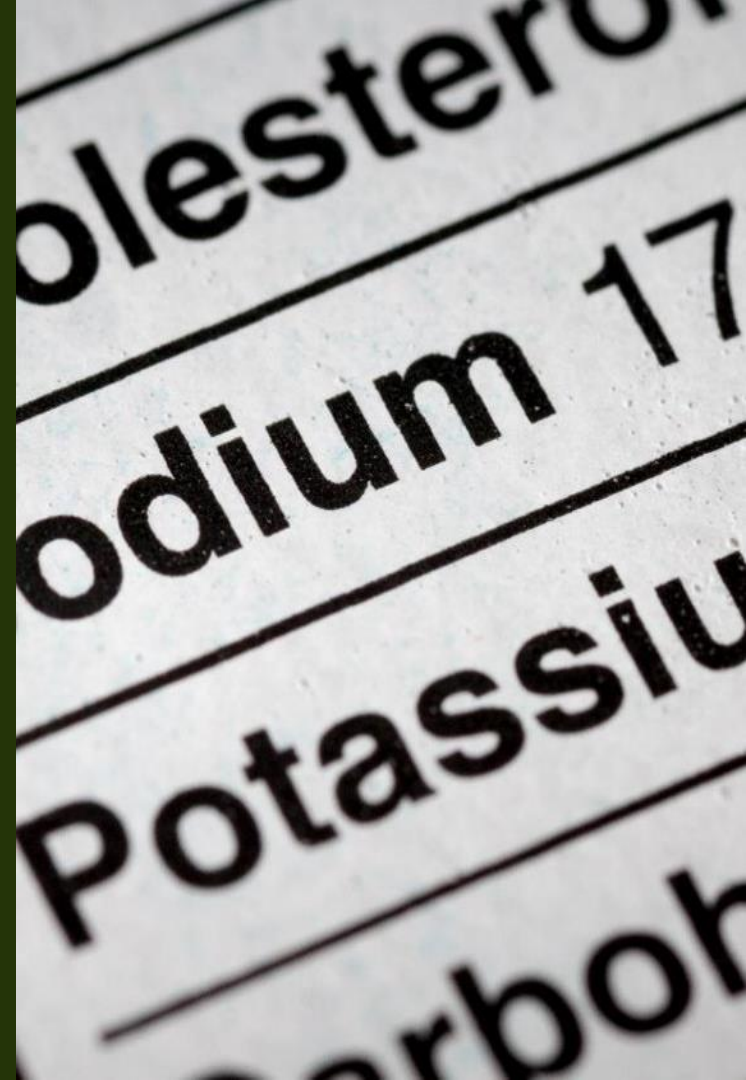
Food

Join the future Human Foods Program and make a difference.

FEATURED

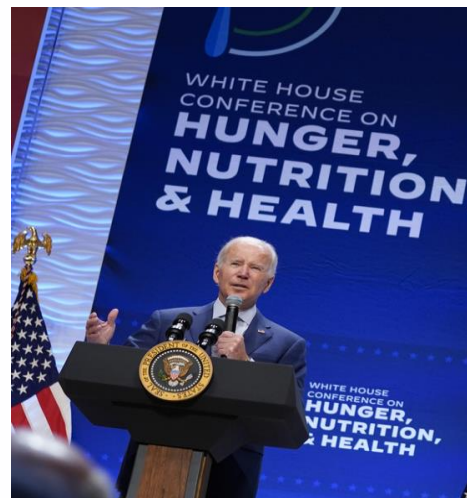
Human Foods Program (and CFSAN) Career Opportunities

Key Nutrition Policy & Food Labeling Initiatives



FDA Accelerates Nutrition Policy & Food Labeling Initiatives

- Ambitious agenda set by White House National Strategy on Hunger, Nutrition & Health (Sept. 2022)
- President's goals: End hunger and increase healthy eating and physical exercise by 2030 to reduce diet-related disease and health-related disparities
- Key areas of focus
 - “Facilitate” lowering sodium content of food
 - Front of Pack (FOP) nutrition labeling
 - “Facilitate” lowering added sugars consumption
 - Finalize “healthy” proposal; develop “healthy” symbol
 - Encourage use of dietary guidance statements



Key Actions on Sodium

- Oct. 2021 FDA issued **voluntary** sodium guidance for processed and restaurant foods with 2.5-year goals for sodium reduction
 - Goal of reducing sodium intake to 3,000 mg/day (12% reduction)
 - Became “effective” April 2024
- Aug. 2024 FDA publishes **voluntary** “Phase II” draft targets
 - 3-year targets (following final guidance publication)
 - Goal of reducing sodium intake to 2,750 mg/day (19% reduction)
 - FDA has not updated its current intake estimate of 3,400 mg/day
 - Same 163 food categories
 - FDA discusses importance of “gradual” reductions and views draft targets as “feasible using existing technology because they are within the range of currently available products”
 - Comments due Nov. 14, 2024



Key Actions on Sodium



- FDA Preliminary Assessment on Phase I Progress
 - About 40% of food categories have already achieved or are within 10% of the Phase I targets
 - Based on data comparing 2010 to 2022 levels; came from publicly available sources (labels, menus, databases aggregating this information)
 - FDA has not analyzed data from 2023 or Jan-Apr. 2024
 - FDA will conduct an assessment of progress ~ every 3 years and will publish a more formal evaluation of the Phase I targets when 2024 data becomes available
 - More than 60% of packaged food categories decreased in sodium, while 25% increased

Sodium Targets: Frozen & Refrigerated Pasta

All figures are in mg per 100 g; RACC for prepared pasta is 140 g

■ Takeaways:

- Important for NPA to comment on whether targets are realistic (particularly for frozen pasta)
- Evaluate your products against the upper bound targets

Category	2010 Baseline	Phase I Sales Weighted Avg. Target	Phase I Upper Bound Target	2022 Baseline	Phase II Sales Weighted Avg. Target	Phase II Upper Bound Target
Frozen Pasta	238 mg	200 mg (16% decrease)	270 mg	255 mg (7% increase)	160 mg (37% decrease!)	270 mg
Refrigerated Pasta	498 mg	450 mg (9% decrease)	580 mg	478 mg (4% decrease)	400 mg (16% decrease)	530 mg



Front-of-Pack Nutrition Labeling

- National strategy directs FDA to propose a “standardized” FOP labeling system
 - CSPI Citizen Petition to FDA (July 2022)
- FDA has conducted consumer research on various FOP nutrition labeling schemes; is subjecting that research to peer review
- Plans to issue proposed rule by end of 2024
- Does FDA have the legal authority to mandate?
 - No express provision in FFDCA or NLEA authorizes
 - Statute grants highly specific authority to mandate a complete set of information in the NFP
 - FDA has stated Facts Up Front icons are nutrient content claims, so FOP labeling is mandatory nutrient content claims, in contradiction of the statute which makes such claims voluntary
 - Impact of *Loper Bright* Supreme Court decision

Examples of FOP Schemes Tested by FDA

PER SERVING

0g SAT FAT 0% DV	45mg SODIUM 2% DV	0g ADDED SUGARS 0% DV
------------------------	-------------------------	-----------------------------

FDA.gov

Nutrition Info Per serving

Saturated Fat	Low
Sodium	High
Added Sugars	Low

FDA.gov

Nutrition Info Per serving

Saturated Fat	High
Sodium	Low
Added Sugars	Low

Nutrition Info
Per serving %Daily Value

Saturated Fat	25%	High
Sodium	5%	Low
Added Sugars	2%	Low

FDA.gov

Nutrition Info
Per serving %Daily Value

Saturated Fat	25%	High
Sodium	5%	Low
Added Sugars	2%	Low

FDA.gov

High In
Added Sugars

FDA.gov

High In % Daily Value
Added Sugars 49%

FDA.gov

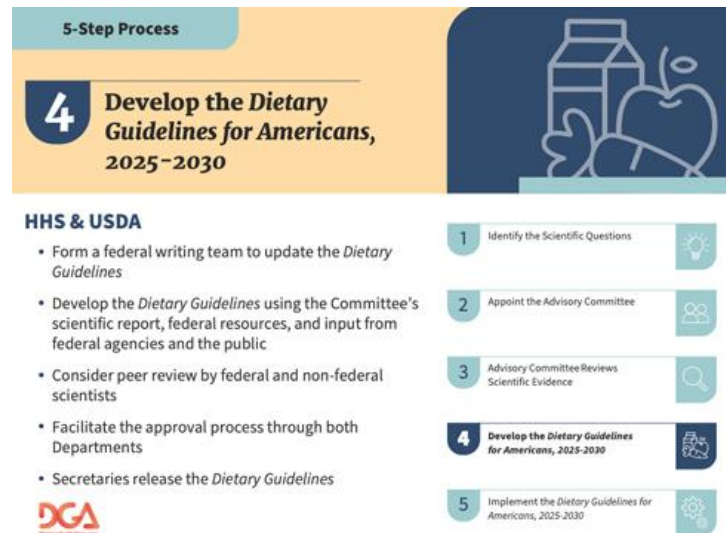
FDA Proposed Rule on “Healthy”



- Two basic requirements:
 - Minimum food group contribution (fruit, vegetable, dairy, whole grains, protein foods)
 - Nutrient limits (vary by food type, but generally):
 - Added sugars no more than 5% DV (some categories 0% DV)
 - Sodium no more than 10% DV
 - Saturated fat no more than 5% DV (1g), though some categories like dairy and nuts receive flexibility
- Proposed definition is *extremely* limiting as to which foods qualify
 - No ability to qualify based on nutrients to encourage
- Comments submitted February 2023
- Compliance date: 3 years after final rule
- On July 16th, FDA submitted the final rule to OMB for review; expected to be published soon

Dietary Guidelines for Americans (DGA)

- Jointly published by HHS and USDA
- Designed to provide advice on what to eat and drink to meet nutrient needs, promote health, and prevent disease
- Generally forms the basis of federal nutrition programs
 - Supplemental Nutrition Assistance Program (SNAP)
 - Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)
- Updated every five years
- DGA 2025-2030 currently in development



Ultra-Processed Foods Ultra-Confusion, or Ultra-Nonsense?



Background on UPF

- Food classification system proposed by researchers in Brazil in 2009
 - “NOVA” system divides foods into four categories based on ingredients and extent of processing:
 1. Unprocessed or natural foods
 2. Minimally processed foods
 3. Processed foods
 4. **“Ultra-processed foods”**
 1. “industrial formulations made entirely or mostly from substances extracted from foods (oils, fats, sugar, starch, and proteins), derived from food constituents (hydrogenated fats and modified starch), or synthesized in laboratories from food substrates or other organic sources (flavor enhancers, colors, and several food additives used to make the product hyper-palatable).”
- *Morris v. Welch Foods Inc.* (argues “yogurt” coated fruit snacks are a UPF and essentially a candy coating; and that yogurt misrepresents healthfulness of the product)

Background on UPF

- Debate in the scientific community about the merit of UPF and the NOVA system
 - Criteria are poorly delineated, creating a significant risk of misclassification of foods
- Proposed NOVA system has been used in studies that purport to assess the correlation between consumption of UPF and obesity/ other health conditions, but:
 - Studies do not assess causation
 - Studies do not isolate the effect of processing of a food – arguably the studies are more directly about nutritional quality of the diet

How Bad Are Ultraprocessed Foods, Really?

They're clearly linked to poor health. But scientists are only beginning to understand why.



MIND & MOOD

Ultra-processed foods? Just say no

New research suggests that ultra-processed foods (UPFs) raise the risk of cognitive impairment and strokes.

June 17, 2024

By **Andrew E. Budson, MD**, Contributor; Editorial Advisory Board Member, Harvard Health Publishing

YOUR HEALTH

From anxiety to cancer, the evidence against ultra-processed food piles up

MARCH 18, 2024 · 5:01 AM ET

HEARD ON MORNING EDITION



UPF and the Dietary Guidelines

- “Ultra-processed food” is not terminology used today in U.S. (or other national) regulations, but this could change in the future
- Proposed Question for the Dietary Guidelines Advisory Committee (2022):
 - *What is the relationship between consumption of dietary patterns with varying amounts of ultra-processed foods and growth, size, body composition, risk of overweight and obesity, and weight loss and maintenance?*
- DGAC finds “limited evidence” that UPF lead to weight gain
 - Only one randomized controlled trial; was of short duration
 - Anticipated result: more research!
- *Childhood Diabetes Reduction Act* introduced in U.S. Senate to require warnings on UPF connecting to weight gain, obesity, and diabetes
 - UPF = “one or more industrial ingredients” (e.g., stabilizers, emulsifiers, added flavors/colors)

UPF and the Dietary Guidelines

1. Statements in the DGAC Scientific Report addressing the relationship, if any, between UPF and body weight, obesity, etc.
2. Statements in the Dietary Guidelines for Americans (2025-2030) discouraging consumption of UPF
3. State and federal policy and law could follow:
 - Warning statements
 - Taxes
 - Advertising restrictions
 - Healthy checkout aisles
 - Many others

EXCLUSIVE

STAT+

**Top FDA officials weighing
regulation of ultra-processed foods,
internal documents show**

Chemical Contaminants



Heavy Metals in Foods for Babies & Young Children (<2)

- April 2022 draft guidance for lead in juices
 - All juices except apple 20 ppb
 - Apple juice 10 ppb
- Draft guidance issued in January 2023 for lead in baby food
 - 10 ppb for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain and meat-based mixtures), yogurts, custards/puddings and single-ingredient meats
 - 20 ppb for root vegetables (single ingredient)
 - 20 ppb for dry cereals
- Draft guidance for cadmium is expected by end of 2024; final lead guidance; inorganic arsenic too

Why it Matters

- FDA's focus on heavy metals in infant & toddler foods will impact other categories
 - Expect end users to adjust specifications for a range of commodities & ingredients
 - Tighter specifications likely to increase costs for affected commodities & ingredients; impacts on supply chains TBD
- Litigation, litigation, litigation
 - Baby food, chocolate, spices
- FDA planning to release HARPC Guidance Chapter 12 on PC's for Chemical Hazards
- FDA seek authority to establish binding contamination limits by administrative order; require product testing; expand mandatory recall authority

CRConsumer
Reports

Lead and Cadmium Could Be in Your Dark Chocolate



States Meddling with Federal Issues



Food & Color Additives in the Crosshairs

- **Ingredient safety on a state-by-state basis?**
 - California banned FDA approved food and color additives in foods as of Jan. 1, 2025
 - Red 3
 - Propylparaben
 - Brominated vegetable oil
 - Potassium bromate
 - Other states are considering similar bans and some of those bans would extend to titanium dioxide
 - California legislature passed a bill banning colors (red 40, yellow 5 & 6, blue 1 & 2, and green 3) in foods offered in schools effective Dec. 31, 2027
 - Bill to Governor Newsom for signature

5 Dangerous Ingredients That Are in Our Food But Shouldn't Be

California is considering banning Red Dye No. 3 and other common additives, which could affect hundreds of foods, even in other states

By Scott Medintz

March 20, 2023



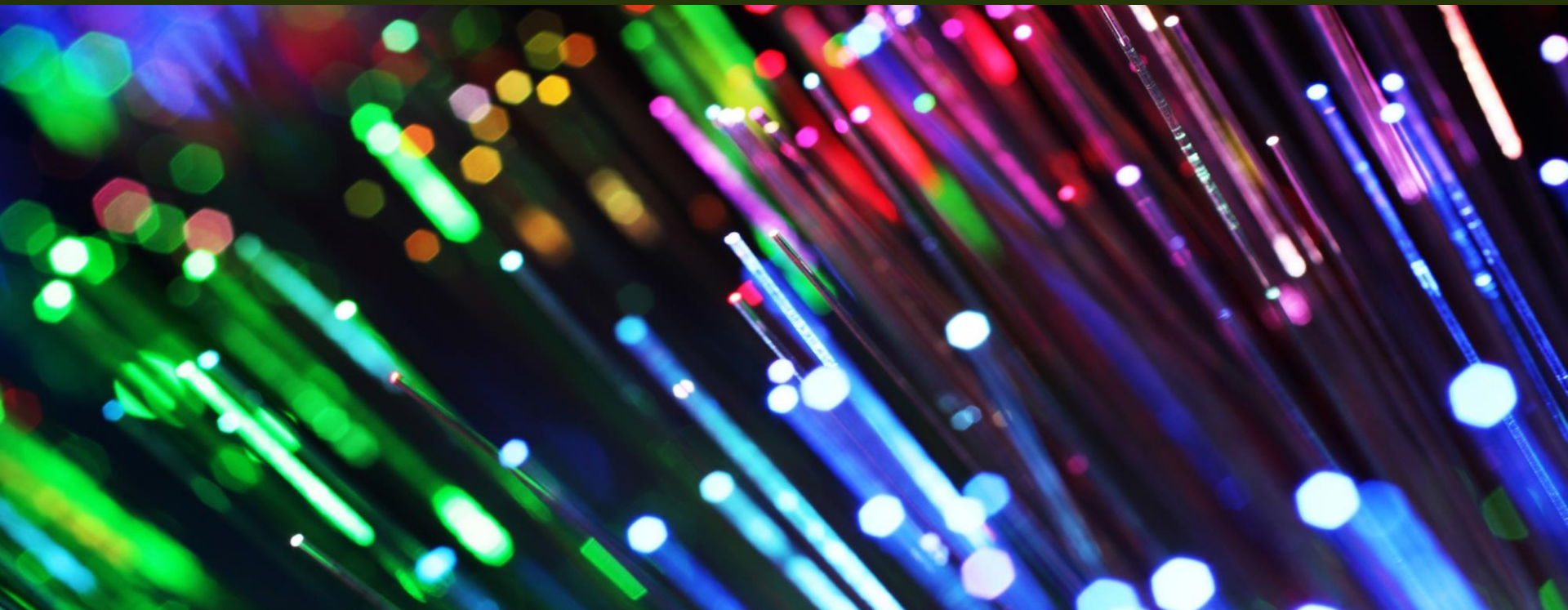
- FDA's "List of Select Chemicals in the Food Supply Under FDA Review"
 - <https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review>
- FDA Public Meeting: Development of an Enhanced Systematic Process for FDA's Post Market Assessment of Chemicals in Food
 - September 25, 2024
 - Discussion paper FDA's proposed process released; questions posed
 - Comments due December 6, 2024

Is Food Safe if it Has Chemicals?

Assessing the safety of additives and other chemicals in food includes scientific study of how much of a chemical is in a food and how much we're likely to eat.



What's to Come?



Planned Guidance and Rulemakings

- Guidance topics include:
 - Closer to Zero
 - Validation of preventive controls
 - Chemical hazards
 - CPG: *Lm* in human foods
 - Labeling of plant-based foods
 - Evaluating low moisture RTE foods following equipment contamination
- Rulemakings:
 - Written assurances
 - SOI issues
 - Salt substitutes
 - General principles for modernizing food standards
 - FOP labeling
 - Healthy final rule



Implications of *Loper Bright Enterprises*

Is this the end of the administrative state?

- Case overruled the administrative law doctrine known as “*Chevron* deference”
- Combined with *Corner Post Inc.*, which affects the statute of limitations for challenging agency actions, results in a sea-change in administrative law
- BUT does not affect everything agencies do!
 - It’s only about what to do when statutes are ambiguous
 - Adjudicative proceedings; agency interpretations of its regulations; agency guidance are NOT affected
 - Rulemaking issues involving whether the agency considered the right issues, explained its position, etc., are NOT affected
 - Agency enforcement of existing requirements is NOT affected



Questions?



Veronica Colas
Counsel, Washington, D.C.

+ 1 (202) 637 6937
veronica.colas@hoganlovells.com



hoganlovells.com

"Hogan Lovells" or the "firm" is an international legal practice that includes Hogan Lovells International LLP, Hogan Lovells US LLP and their affiliated businesses.

The word "partner" is used to describe a partner or member of Hogan Lovells International LLP, Hogan Lovells US LLP or any of their affiliated entities or any employee or consultant with equivalent standing. Certain individuals, who are designated as partners, but who are not members of Hogan Lovells International LLP, do not hold qualifications equivalent to members.

For more information about Hogan Lovells, the partners and their qualifications, see www.hoganlovells.com.

Where case studies are included, results achieved do not guarantee similar outcomes for other clients. Attorney advertising. Images of people may feature current or former lawyers and employees at Hogan Lovells or models not connected with the firm.

© Hogan Lovells 2024. All rights reserved.