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Regulatory Update

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Agenda

- FDA Structure
- FDA Labeling Initiatives
- Contaminants
- State Meddling
- Litigation
- Other Fun



FDA's Foods Program Rebuilding or Rebranding?



Department of Health and Human Services
Food and Drug Administration
Human Foods Program

Commissioner of
Food and Drugs

Deputy Commissioner
for Human Foods

Office of
Quality Assessment

Office of
Executive Programs
& Strategic Planning

No
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Office of
Microbiological
Food Safety

Office of
Food Chemical Safety,
Dietary Supplements
& Innovation

Office of
Resource
Management

Office of
Risk Prioritization &
Surveillance Strategy

Office of
Communications,
Education &
Engagement

Office of
No
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Office of
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Safety System
Partnerships**

Office of
Policy & International
Engagement

Office of
Laboratory
Operations &
Applied Science***

Office of
Preparedness
& Response

*Includes Office of Critical Foods

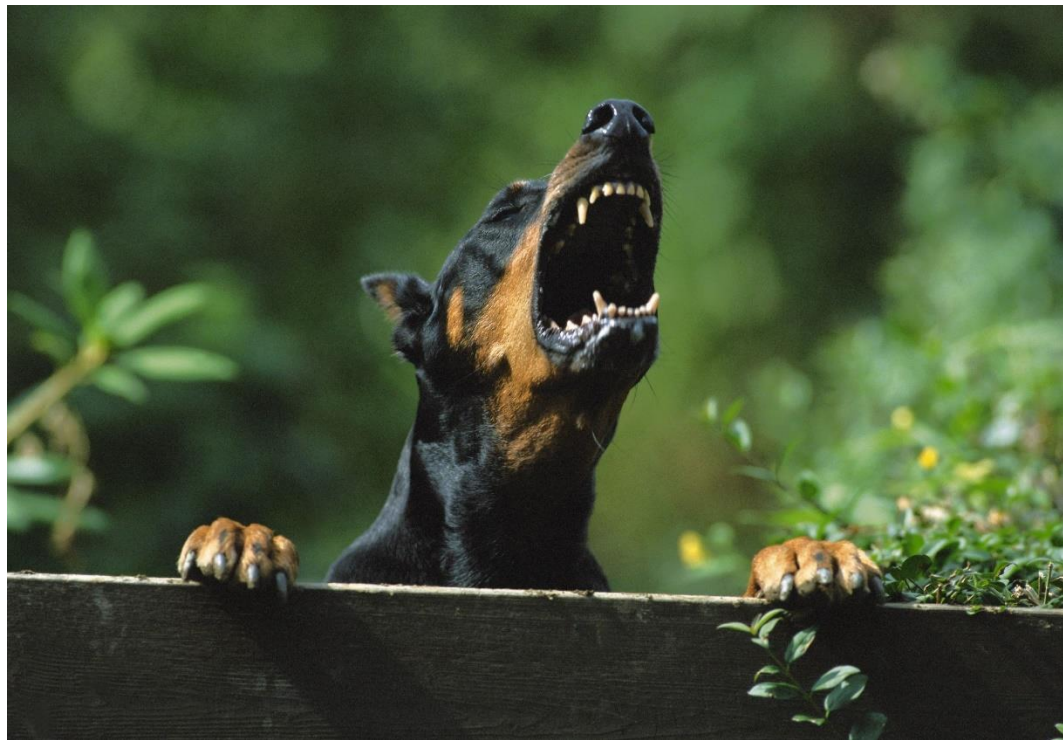
**OIFSSP will work in close coordination with the Center for Veterinary Medicine

***OLOAS will work in close coordination with the Office of the Chief Scientist and Center for Veterinary Medicine

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



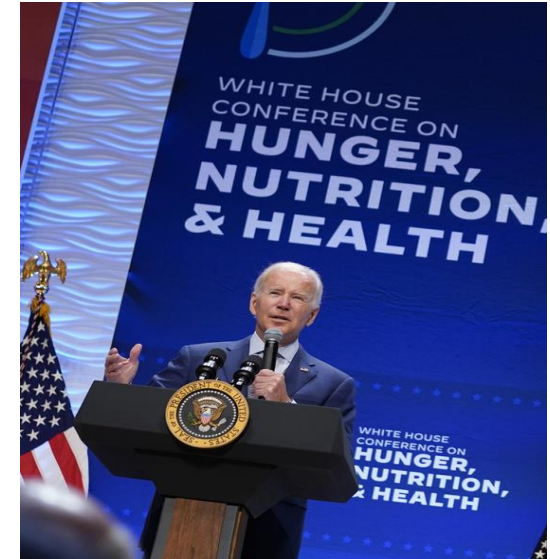




Key Nutrition Policy & Food
Labeling Initiatives

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

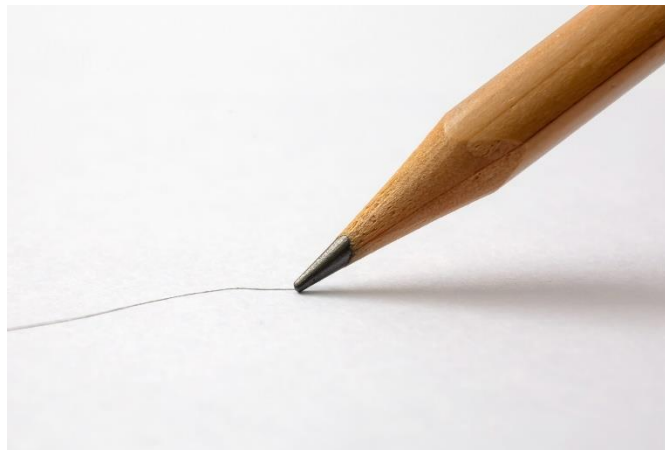
- Oct. 2021 FDA issued “VOLUNTARY” sodium guidance for processed and restaurant foods with 2.5-year goals for sodium reduction for
 - 163 food categories
 - FDA sets
 - Sales weighted mean for each category
 - Upper bound levels
- The Upper Bound level is the maximum recommended sodium level for any individual product in the category
- **Becomes “effective” April 2024**



Four Mind-States for Sodium Reduction



Put

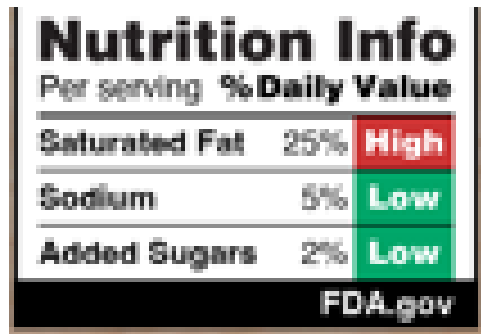
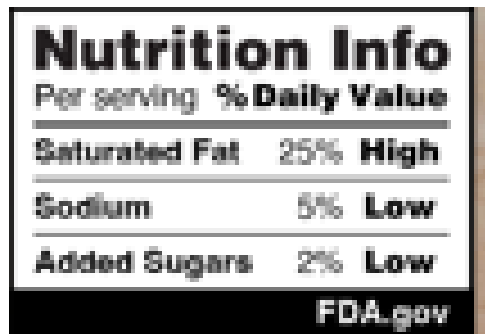
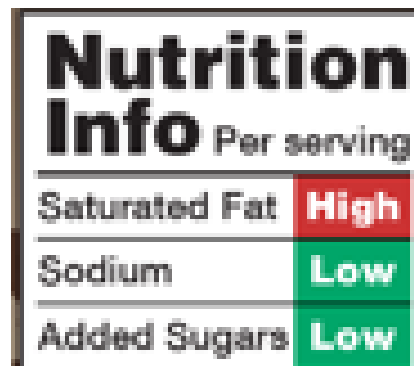
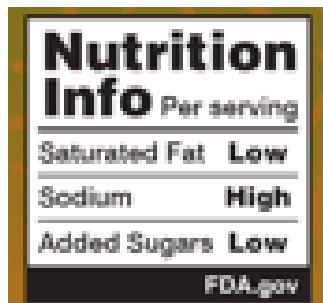
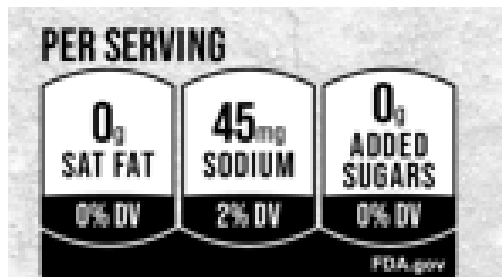


Front-of-Pack Nutrition Labeling

- National strategy directs FDA to propose a “standardized” FOP labeling system (e.g., a star rating or traffic light symbol)
 - CSPI Citizen Petition to FDA (July 2022)
- FDA recently announced that it will be conducting consumer research on various FOP nutrition labeling schemes
- Does FDA have the legal authority to mandate?



FOP Examples of FDA Logos Being Tested



What about Added Sugars?


- National strategy directs FDA to “begin assessing the evidence base for further strategies” to reduce consumption
- FDA planning to issue draft guidance on the use of nutrient content claims about added sugars on labels within the next 12 months
- Could “voluntary” added sugars targets by food category be far behind?
- Plaintiff’s bar remains interested in sugar
 - LeGrand v. Abbott Laboratories (Ensure brand shakes) (survives MTD)
 - Reynolds v. Coca Cola (Minute Maid 100% juice)



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
- New definition is *extremely* limiting as to which foods qualify
 - No ability to qualify based on nutrients to encourage
- Comments submitted by Feb. 16, 2023
- Compliance date: 3 years after final rule





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”**



Contaminants

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

- April 2022 draft guidance for lead in ALL juices (not limited to children <2)
 - 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

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

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

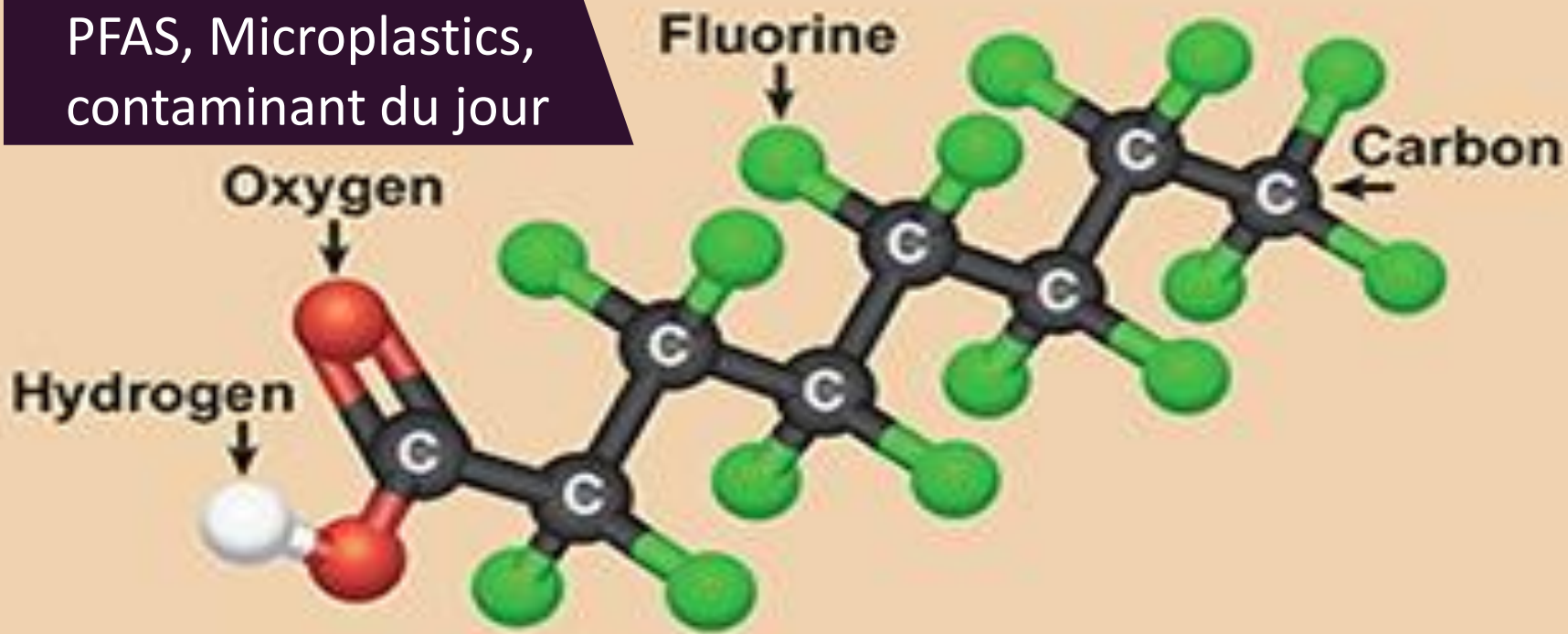


Emerging Developments to Watch

- States are passing laws defining use of “recycled” on labels and mandating recycling content requirements
- Extended Producer Responsibility (EPR)
- States bring action against food companies for environmental contamination (food and beverage waste in state rivers)



PFAS, Microplastics,
contaminant du jour



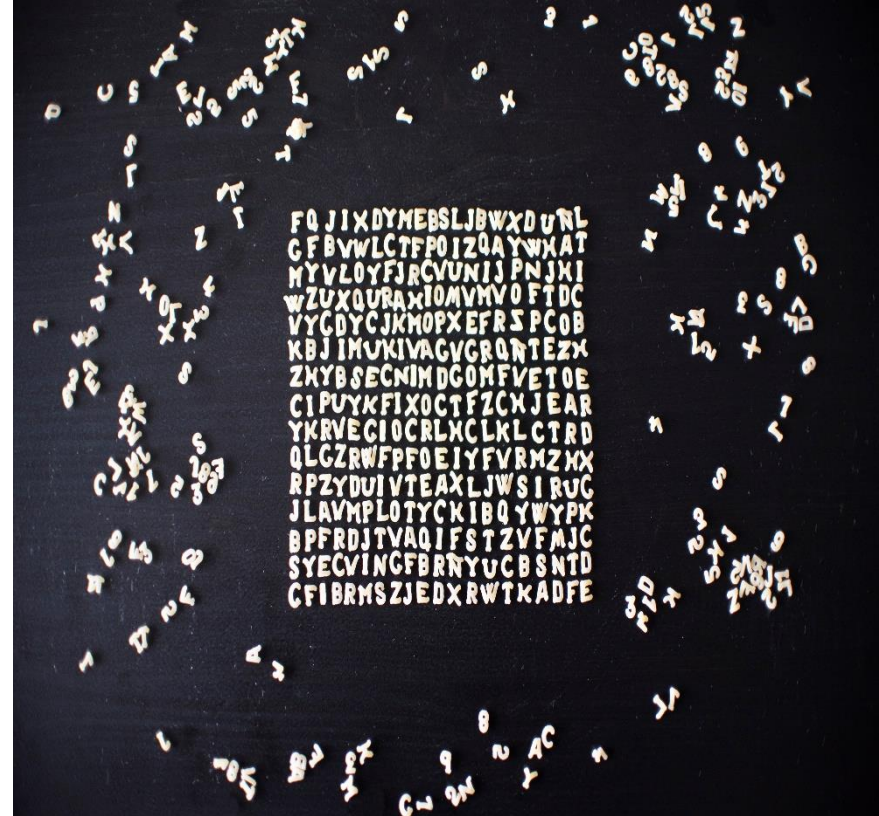
EPA Drinking Water Levels

PFAS	Level
PFOA	4 ppt
PFOS	4 ppt
PFHxS	10 ppt
PFNA	10 ppt
GenX Chemicals	10 ppt



New Focus on Plastics and Microplastics

- Microplastics in foods and beverages
- PVOH (identified as a microplastic) in environment, foods, beverages
- Phthalates
- Bisphenyls
- Alphabet soup of other contaminants TBD



An aerial photograph showing a tractor with a red and yellow body moving through a field. The field is divided into two main sections: a large green section on the left and a yellow section on the right. The tractor is positioned in the yellow section, moving from the top right towards the bottom left. The image shows distinct tracks and patterns in the crops, suggesting a recent agricultural operation.

Food Safety Quick Hits

FDA Turns Up the Heat on Inspections and Enforcement

- FDA inspections and enforcement expected to ramp up in aftermath of CFSAN criticism
- Higher level of scrutiny during domestic inspections, moving beyond “educate while we regulate”
- Expected areas of focus:
 - Allergen preventive controls
 - Sanitation preventive controls
 - Validation for process preventive controls
 - Foundational cGMP issues



Draft Guidance

- May 2023 Draft Guidance on Labeling and Cross Contact with Major Food Allergens
 - Sets FDA expectations on “may contain” and other advisory statements
 - Data driven to justify use of “may contain”
 - Must demonstrate not being used in lieu of GMPs
- Fall 2023 – Allergen Control Program Guidance
 - Sets FDA expectations on manufacturing and supply chain controls



Overview of the Traceability Rule

- Creates new recordkeeping requirements for “high risk” foods
- Food Traceability List identifies high risk foods:
 - Nut butters;
 - Cheese other than hard cheese
- Requires entities that perform certain events in the food supply chain to establish and maintain records containing certain information (Key Data Elements)
 - Critical Tracking Events = harvesting, cooling, initial packing of raw agricultural commodities, first land-based receiving, **transforming, receiving, shipping**
- FDA requires most entities to provide the agency with an electronic, sortable spreadsheet within 24 hours of request by FDA in certain situations
- Compliance date = January 20, 2026
 - FDA will not begin routine inspections until 2027
 - Supply chain partners may ask for information in advance of compliance date

An aerial photograph of agricultural fields. The left side shows a green field with distinct diagonal furrows. The right side shows a bright yellow field, likely rapeseed, with a tractor visible in the upper right quadrant. A dark purple trapezoidal shape is overlaid on the bottom left corner, containing the text 'Litigation Trends'.

Litigation Trends

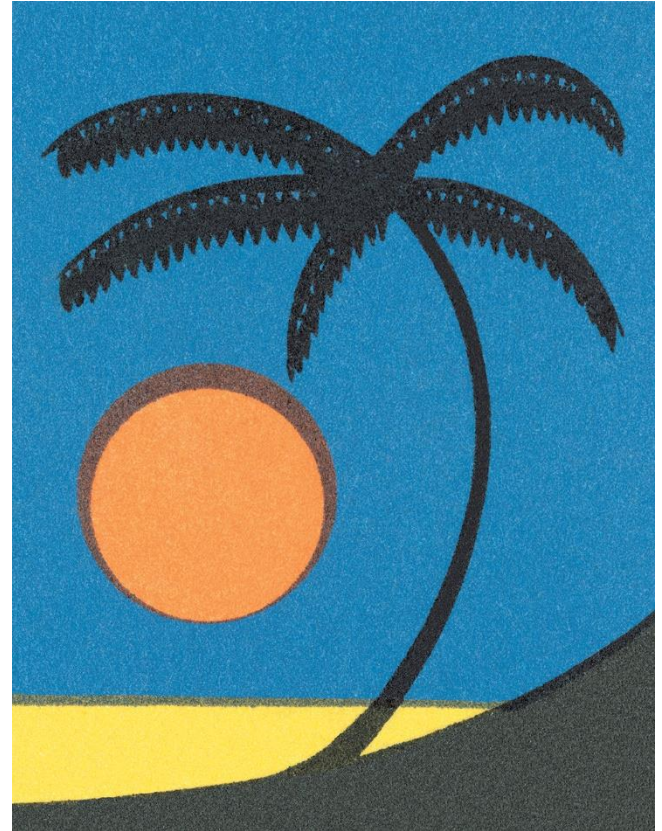
Food Industry Remains Under Assault

- Class action lawyers are becoming increasingly creative in filing causes of action
 1. Claims
 2. PFAS and other Contaminants
 3. Environmental
- FDA/DOJ continue to pursue criminal (misdemeanor or felony) against food industry



Litigation Trends Proposition 65

- Many heavy metals and plastics are on Prop 65
- NGO reports frequently trigger Prop 65 challenges
- Progress is being made on 1st Amendment Challenges
 - 9th Circuit finds glyphosate warnings misleading
 - 9th Circuit assessing whether acrylamide warnings are misleading



Cal Chambers Lawsuit

- August 2023 court set the schedule
 - Fact Discovery Closed: 1/2024
 - Expert reports have been exchanged
 - Expert depositions: 4/15-4/23
 - Discovery Closes: 4/24
 - Summary Judgement: plan to file in May 2024
 - Hearing: 9/19
- But,
 - OEHHA is proposing another safe harbor warning;
 - The AG is asking the court to delay the lawsuit or defer the scheduling





Questions?



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