

# WASHINGTON UPDATE

NPA Annual Meeting March 17, 2025

> Veronica Colas, Partner Hogan Lovells US LLP

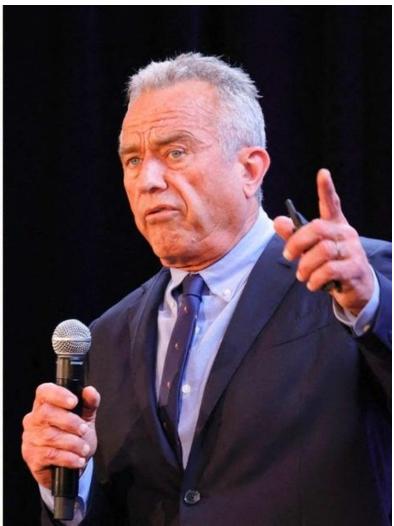
# Agenda

- New Administration
- FDA Updates, Updates Updates, & Updates
- International Trade Update
- State Meddling



# **Impact of the Election**







MAHA starts today?

### What is the MAHA Agenda?

- The Chronic Disease Epidemic
  - MAHA's policy focus advocates for a comprehensive national strategy to combat the chronic disease epidemic, which includes addressing the root causes such as poor diet, environmental toxins, and inadequate healthcare. The PAC supports policies that promote preventative healthcare, increase access to nutritious food, and reduce the environmental factors contributing to chronic illnesses like cancer, diabetes, and heart disease.
- Regenerative Agriculture
  - MAHA champions regenerative agriculture as a solution to many of America's health and environmental challenges. This includes supporting policies that incentivize sustainable farming practices, improve soil health, reduce chemical usage, and increase biodiversity. Regenerative agriculture not only produces healthier food but also contributes to carbon sequestration and the fight against climate change.
- Habitat Preservation
  - Protecting America's natural habitats is crucial for both environmental sustainability and public health.
     MAHA supports policies that preserve and restore natural ecosystems and curb the destruction of vital
     habitats caused by industrial and agricultural expansion. This includes advocating for stronger
     environmental regulations and enforcement to prevent habitat loss and degradation.

### What is the MAHA Agenda?

- Combatting Corporate Corruption
  - MAHA is committed to exposing and dismantling the corporate takeover of government agencies that are supposed to protect public health and the environment. The PAC supports policies that increase transparency and accountability in government, reduce the influence of corporate money in politics, and ensure that regulatory agencies operate in the public interest, not at the behest of corporate donors.
- Removing Toxins from the Environment
  - One of MAHA's top priorities is the elimination of harmful chemicals and toxins from America's food, water, and air. MAHA advocates for comprehensive testing and monitoring of environmental toxins to ensure that all Americans have access to clean, safe, and healthy living conditions.



#### - Post







I am thrilled to announce Robert F. Kennedy Jr. as The United States Secretary of Health and Human Services (HHS). For too long, Americans have been crushed by the industrial food complex and drug companies who have engaged in deception, misinformation, and disinformation when it comes to Public Health. The Safety and Health of all Americans is the most important role of any Administration, and HHS will play a big role in helping ensure that everybody will be protected from harmful chemicals, pollutants, pesticides, pharmaceutical products, and food additives that have contributed to the overwhelming Health Crisis in this Country. Mr. Kennedy will restore these Agencies to the traditions of Gold Standard Scientific Research, and beacons of Transparency, to end the Chronic Disease epidemic, and to Make America Great and Healthy Again!

4:13 PM · Nov 14, 2024 · **158.4M** Views

# Which of any of these will rise to the top of the administration's priorities?

- Processed foods:
  - Ban food additives and chemicals,
     such as synthetic colors and seed oils
  - Ban UPF from school lunches "immediately"
  - SNAP (food stamp) reform
  - Broader action on UPF

- Clean house
  - FDA nutrition staff "has to go"
- Allow sale and distribution of raw milk in interstate commerce
- Remove fluoride from public water
- Toxic elements
  - Heavy metals
  - Revise pesticide standards

# What tools can the administration leverage to act quickly?

- Executive Orders
- Delaney Clause
- Dietary Guidelines for Americans
  - HHS and USDA will reissue at the end of 2025
  - Serve as the cornerstone for federal nutrition policy
- Congressional action to ease path on food dyes or other additives; GRAS reform; reform the SNAP program/ school lunches/ WIC foods
- Use the bully pulpit/ public health advisories/ social media
- Leverage state legislatures to ban ingredients
- Emergency orders revoking EPA pesticide tolerances
- Congressional Review Act withdraw the healthy final rule and issue a new rule on steroids? Or keep the final rule and build on it?

## Leadership Changes at HHS and FDA

- Robert F. Kennedy Jr. confirmed as HHS Secretary
- Dr. Martin Makary nominated as FDA Commissioner
- Jim Jones resigns as Deputy Commissioner for the FDA Human Foods Program
- Kyle Diamantas named Acting Deputy Commissioner for Human Foods
- MAHA Commission established
  - Make Our Children Health Again Assessment due May 24; Strategy due August 12
- Key Executive Orders
  - 10:1 Deregulatory Order
  - 4:1 Hiring Order
  - MAHA Commission Order
  - EO asking agencies to identify regulations that are "unlawful", "undermine the national interest", or impose "undue burdens" on technological innovation and economic development

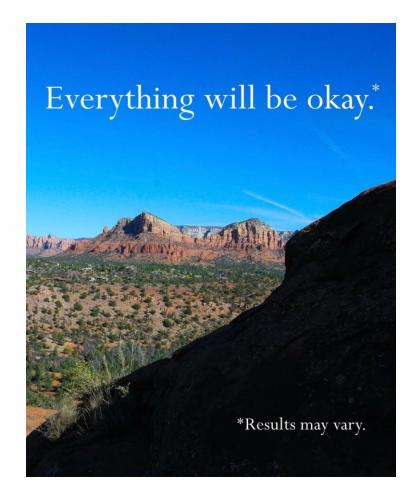






# How can food companies prepare for the new administration?

- Prepare for the unexpected; stay nimble
- Think proactive, not reactive and know your priorities
  - Identify deregulatory priorities
  - Federal legislative package
  - Litigation priorities
- Update your communications approach
- Stay engaged with your trade associations





# FDA Finalizes Healthy Definition

- Final Rule issued Dec. 27, 2024
- The final rule retains the proposed criteria of permitting healthy claims for foods containing:
  - A certain quantity of food group equivalents (FGE) (such as fruits, vegetables, whole grain, dairy, and protein foods)
  - No more than specified amounts of added sugars, sodium, and saturated fat, referred to as nutrients to limit (NTL)
- Provides much needed flexibility for added sugars and sodium
- Effective date currently stayed until April 25,
   2025 as the agency reviews the final rule
- Remember my prediction from 2024?





# Front of Pack Labeling

- FDA issues proposed rule on front of package labeling on Rule on Front of Pack Nutrition Labeling on January 16, 2025
- Would require front of pack nutrition labeling on almost every food that bears an NFP today
- Would require placement on top 1/3 of the front panel (principal display panel)

Nutritio Per serving 5 cookies	%	nfo Daily /alue
Saturated Fat	25%	High
Sodium	5%	Low
Added Sugars	10%	Med
	FDA.gov	



#### Placement and Prominence

(Note: Pasta will typically be identified as "Low" in all three nutrients)





#### **Key Actions on Sodium**

- Phase I guidance on voluntary sodium reductions – finalized October 2021; effective April 2024
- Phase II draft guidance issued August 2025
  - Intended to reduce sodium to 2,750 mg/day
  - 3 years to implement (once finalized)
- Only covers stuffed/filled pasta, not dry pasta
- Remember what I said in 2024?





### FDA Opens Flood Gates on Guidance Documents

- On January 6, 2025 FDA issues multiple draft and final guidance documents
  - Draft Guidance: Labeling of Plant-based Food
     Alternatives to Animal Derived Foods
  - Draft Guidance: Management of Environmental
     Pathogen Hazards for Low-Moisture Ready-to-Eat Foods
  - Final Guidance: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens
  - Final Guidance on Q&A for Major Food Allergens
  - Final Guidance for Industry on Action Levels for Lead in Processed Food Intended for Babies and Young Children





#### Draft Guidance on Plant Based Foods

- Applies to plant-based alternatives to animal-derived foods (eggs, dairy products, meat & poultry)
- Recommends that the product name should identify the specific plant source
  - "Soy yogurt," "almond yogurt," "chickpea and lentil based fish sticks,"
     "chia and flax seed eggless cramble," "black bean mushroom veggie patties," and "plant-based soy bacon"
  - Standardized terms need to be qualified such as "soy-based cheddar cheese"
- Terms such as "vegan," "plant-based," and "animal free" can be used but must be accompanied by the plant source
- Does not require disclosure if nutritionally inferior
- Comments due May 7, 2025





# Final Allergen Guidance Documents

- Final Guidance: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens
  - Largely tracked draft guidance
  - Set criteria for safety assessments for non-major food allergens
- Final Guidance on Q&A for Major Food Allergens
  - FDA updates list of tree nuts and removes coconut, kola nut, and other nuts that do not meet criteria for severity and prevalence
  - FDA states: allergen information must be limited to the major food allergens
  - For those of you listing coconut in allergen information statement......



# Final Guidance on Lead in Foods for Children <2 yrs

- FDA finalizes guidance on lead levels for products intended for children under 2
- Tracks levels in draft guidance
  - Fruits and vegetables: 10 parts per billion (ppb)
  - Grain and meat-based mixtures: 10 ppb
  - Yogurts, custards/puddings: 10 ppb
  - Single-ingredient root-based vegetables: 20ppb
  - Dry infant cereals: 20 ppb



#### Closer to Zero Take II

- FDA has yet to issue guidance levels for cadmium, mercury, inorganic arsenic
- FDA will continue its work in this space
- Why should we care?



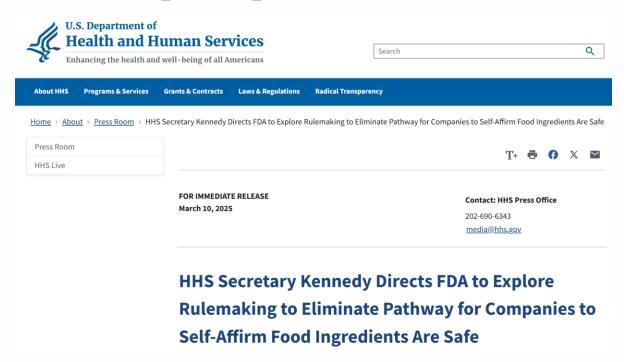
#### FDA Bans Red 3 in Food

- On January 15, 2025 FDA revoked the authorization for the use of Red 3 for use in foods
- Becomes effective January 15, 2027 for foods
- FDA recognizes Red 3 is safe and does not pose a risk of cancer for humans
- FDA revoked Red 3 as a matter of law because the Delaney Clause of the FFDCA prohibits FDA from approving color additives that have been shown to cause cancer in humans
- FDA has concluded the data show Red 3 has been shown to cancer in rodents via a mechanism of action that does not exist in the human body



#### Self-GRAS Under Fire

- RFK has asked FDA to explore rulemaking that would end the ability to use the "self-GRAS" process without a notification to FDA
- Notably, does not reference legislation
- Key questions: resources & preemption



# International Trade Updates



# Trump 2.0 – DAY 1 – The "America First Trade Policy"

- Executive Memorandum calls for top-to-bottom department review of U.S. trade and economic policy with reports by April 1 addressing, among others:
  - Possible "global supplemental tariff" to address trade deficits
  - Establish "External Revenue Service"
  - Apply Trade Authorities (Sections 201, 301, 337, and IEEPA) to address "unfair trade practices by other countries"
  - Conduct new Section 232 investigations
  - Review and assess effectiveness of Section 232 exclusions, exemptions, and other import adjustment measures on steel and aluminum
  - **Reevaluation of USMCA** (ahead of July 2026 joint review) lack of agreement means termination in 2036
  - Review and possibly revise existing trade and sectoral agreements and negotiate new trade and sectoral agreements
  - Review/revise AD/CVD rules
  - Address \$800 de minimis exemption for revenue loss/risk (building on Biden Administration rulemaking restricting availability (201, 302, 232) and enhanced reporting (10-digit HTS) as key to "enhanced entry process"



## Trump 2.0 –Early Trade Actions

- In the first 30 days of the Administration Trump Trade Actions Have included:
  - Canada IEEPA Tariffs (25%) on March 4 to address illegal immigration and fentanyl smuggling USMCA origination exemption and potash reduction on March 7
  - **Mexico IEEPA Tariffs (25%) on March 4** to address illegal immigration and fentanyl smuggling USMCA origination exemption on March 7
  - China IEEPA tariffs (10% February 4 raised to 20% March 4)
     to address illegal immigration and fentanyl
  - **Steel and Aluminum Section 232** 25% tariffs effective March 12 all countries covered and all exclusions, quotas, tariff rate quotas terminated
  - Timber, Lumber Section 232 Investigation Initiated March 1
  - Copper Section 232 Investigation Initiated March 1
  - Section 301 China Shipbuilding USTR determination January
     23 further proceedings



#### Trump 2.0 – What's Next?

#### Retaliatory tariffs

- EU: begin in April and target a range of U.S. products including food and agricultural goods
- Canada: reciprocal tariff against steel and aluminum as well as additional imported U.S. goods, effective March 13
- **China:** second tranche started March 10, with a heavy focus on food & agricultural goods
- **Mexico:** to come?
- Trump Reciprocal Tariffs Proposal April 2 based on Section 301 or IEEPA? Tariffs, VAT, currency manipulation, non-tariff barriers





#### **Ultra Processed Foods**

- Based on NOVA food classification system
  - Unprocessed and minimally processed
  - Processed culinary ingredients
  - Processed foods
  - Ultra processed foods
- There are NO regulatory definitions
- Pictures courtesy of Google....



# Martinez vs Multiple Food Companies

- On December 10, 2024 Morgan & Morgan files a lawsuit against
  - Kraft Heinz,
  - 2. Mondelez,
  - Post Holdings,
  - Coca-Cola,
  - PepsiCo,
  - General Mills,
  - 7. Nestle,
  - Kellanova,
  - WK Kellogg Co.,
  - 10. Mars, and
  - 11. ConAgra Brands

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IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY

> CIVIL ACTION - LAW JURY TRIAL DEMANDED

**DECEMBER TERM, 2024** 

CIVIL NO.

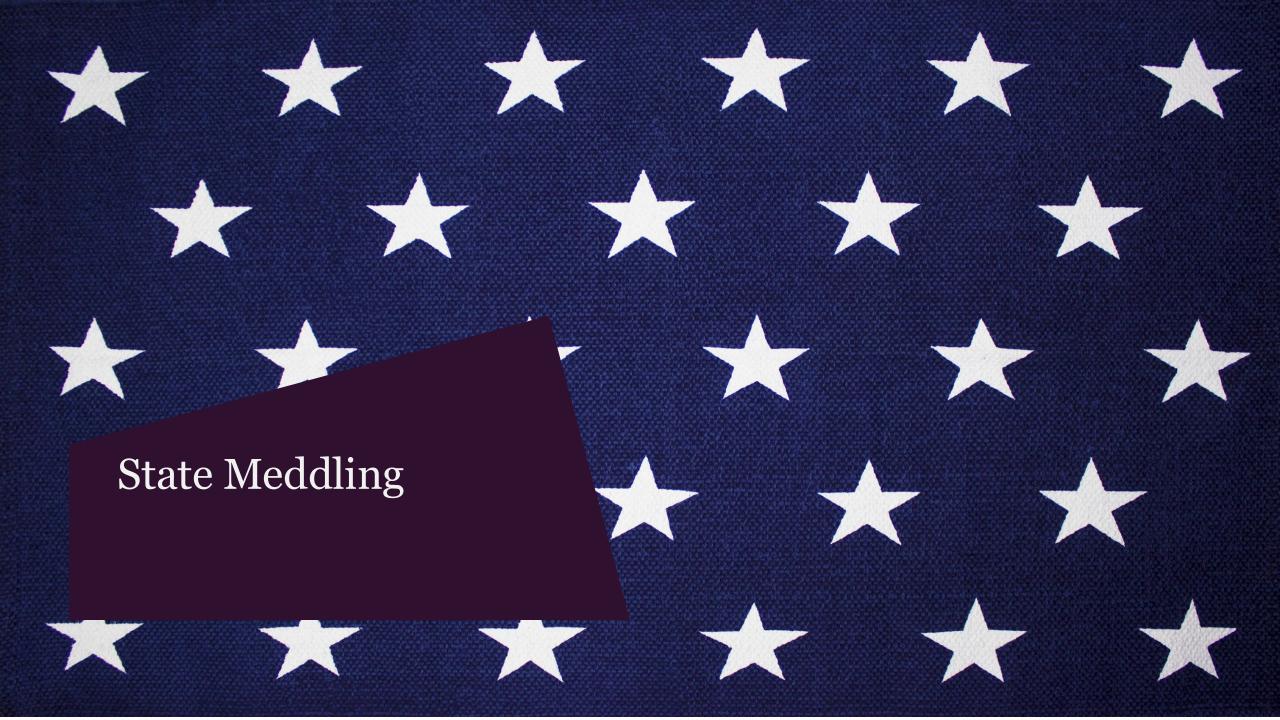
BRYCE MARTINEZ

Plaintiff,

KRAFT HEINZ COMPANY, INC.

One PPG Place.

Pittsburgh, Pennsylvania 15222



#### States Put Pressure on FDA to Act

- States have stepped into the MAHA movement
  - Potential waiver applications for SNAP program limit ultra-processed foods or sugar-sweetened beverages
  - Proposed bans on certified color additives either generally or in schools – 30+ states!
    - CA ban on Red 3 effective Jan. 2027
    - WV legislation would ban most certified colors starting in 2028 (and this August for foods in schools)
  - Texas proposed legislation to require warning statements for foods containing ingredients/colors banned in other countries; Florida also considering a warning statement
- Role of federal preemption?



# Extended Producer Responsibility (EPR)

### Who is responsible?

- Traditionally:
  - Municipalities → Taxpayers
- **EPR** assigns producers the responsibility for the end-of-life of their products (and packaging)
- **EPR**+ seeks to accomplish other policy goals (e.g., waste reduction, less plastics usage)



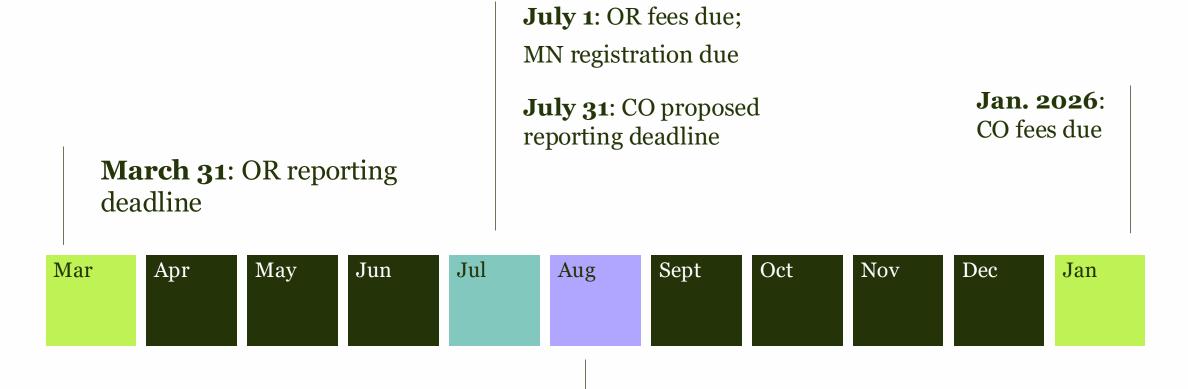
#### **EPR Laws**

## **Key Elements**

- Covered Products
  - Focus on single-use packaging
  - Many states cover B2B sales
- Covered Producers
  - Manufacturers, brand owners/licensees, importers/distributors
- Producer Responsibility Organization
- Fees and Reporting
- EPR+ Targets



# 2025 Timeline: Next Steps



**Aug 31:** CA proposed reporting deadline

# Producer Reporting

# Register ->

- Initial Registration
- Participant Producer Agreement (PPA)
- State Addenda

#### Report

Prepare and submit supply data

#### Pay

- Prepare budget
- Pay fees to CAA

#### On March 31, producers in Oregon must report total supply (in lbs.) by material category =

[Supply volume] x [Packaging weight\*]

\*CAA provides guidance to registered producers on accepted methodologies to calculate packaging weights.

#### **Estimating total fees =**

[Fee rate for material category (provided by CAA)] x [Full year reported supply (in lbs.) for that category]

#### **EPR Laws**

#### **Compliance Considerations**

- CA and MN laws are most rigorous EPR laws in terms of substantive requirements to change packaging; other laws focus largely on fees & reporting
- Circular Action Alliance (CAA) selected as the PRO in CA, CO, and MN; expected to serve as the PRO in other states
  - Registration with CAA suffices for all states as initial registration with PRO
  - CAA has issued guidance and is expected to look for ways to harmonize reporting and compliance across states
- Threshold question: are you a covered "producer"?
  - Laws generally default to covering the **brand owner**, but not always (e.g., if no covered party in the U.S., importer may be covered)

#### **Next Steps**

- 1. Are you a covered producer?
- 2. Have you joined the PRO?
- 3. Have you identified your covered materials?
- 4. Do you have a cross-functional team assembled that can provide the data needed for reporting? (packaging engineering, R&D, procurement, finance/tax, legal & regulatory)
- 5. Have you started to evaluate future packaging options that (a) will meet the recyclable criteria in the state; (b) will meet the state's compostable criteria; and/or (c) use less packaging material?

#### Headwinds

- What am I watching?
  - Ban food additives and chemicals, such as synthetic colors and seed oils
  - Ban UPF from school lunches "immediately"
  - −SNAP (food stamp) reform
  - -GRAS reform
  - -Broader action on UPF
  - -Heavy metals
  - Class action litigation linked to chronic disease



\*Drawn by AI

#### What about the Tailwinds?

- Keep your eye on DOGE and deregulatory initiatives
- I have faith in the system
- The industry
- All of you.....



\*Drawn by AI



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