

# Labeling and Current Regulations

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# Topics to Cover

- **FDA**
  - Plant-based milk alternatives
- **FSIS**
  - Meat and poultry products made using animal cell culture technology
  - Generic label approval expansion
  - Animal raising and environmental claims
  - Processed products that contain nitrate or nitrite
  - Voluntary “Product of the USA” claims
- **AMS**
  - U.S. Origin
  - Bioengineered
- **Prop 12 and Q3**

# Plant-Based Milk Alternatives

*“an almond doesn’t lactate” – Former FDA Commissioner Dr. Scott Gottlieb*

- [Nature or Source] + [Beverage/Drink or Milk]
  - “Dairy-free” or “non-dairy” claims encouraged
- “Soy Milk” or “Almond Milk” with a nutrient composition different than milk
  - Recommends “voluntary nutrient statement”
- “Soy Beverage” or “Almond Drink” and no claims comparing to milk
  - “Voluntary nutrient statement” recommendation does not apply

# Cell-Cultured Meat and Poultry

- Labels must be truthful, accurate, and not mis-leading
- FSIS and FDA coordinating to adopt a naming convention
  - Will need to consider blended products and use as an ingredient
- FSIS will consider the preferences of the
  - cellular agriculture industry,
  - traditional agriculture industry, and
  - consumer groups.

# Generic Label Approval Expansion

- Effective March 20, and includes:
  - Products only intended for export that deviate from domestic labeling requirement.
  - Products that receive voluntary FSIS inspection.
  - “Organic” claims that appear in a product label’s ingredient statement, which designate an ingredient as certified “organic” under the Agricultural Marketing Service National Organic Program. Claims certifying a total product as organic will still require sketch approval.
  - “Geographic landmarks” displayed on a product label, such as a foreign country’s flag, monument, or map.
  - “Negative” claims made on product labels that identify the absence of certain ingredients or types of ingredients, such as “No MSG Added,” “Preservative Free,” or “Gluten Free.” However, certified negative claims, such as “Certified Gluten Free by XYZ;” negative claims that fall under animal raising claims, such as “no antibiotics administered;” and negative claims relating to genetically modified ingredients will still require sketch approval.
- **FSIS will no longer review generically approved labels voluntarily submitted to the agency.**

# Animal Raising and Environmental Claims

- Petition of Note
  - 2022 – People for the Ethical Treatment of Animals
    - no longer allow animal raising claims on FSIS-regulated products
- 2019 – Updated animal raising claims guidance

# Natural Sources of Nitrates and Nitrites

- Petition of Note

- 2019 – Center for Science in the Public Interest

- prohibit the statement "No Nitrate or Nitrite Added" and "Uncured" in the labeling of products using any source of nitrate, require a “nitrates or nitrites added” disclaimer
    - FSIS Response – *“FSIS intends to -- prohibit the statements, “No Nitrate or Nitrite Added” and “Uncured,” on products that have been processed using any source of nitrates or nitrites. FSIS also intends to approve non-synthetic sources of nitrates or nitrites as curing agents. -- FSIS intends to -- establish new definitions for “Cured” and “Uncured.””*

# Product of the “U.S.A.”

- Current state
  - the product is processed in the U.S.
- Petitions of Note
  - 2018 – Organization for Competitive Markets
    - if significant ingredients are of domestic origin
  - 2019 – U.S. Cattlemen’s Association
    - If derived from animals that have been born, raised, and slaughtered in the United States
    - FSIS Response – *“FSIS has decided to initiate rulemaking to limit “Product of USA” -- to the labeling of meat products from livestock that were slaughtered and processed in the [U.S.]”*
  - 2021 – National Cattlemen’s Beef Association
    - eliminate broad Product of USA labeling claims but continue to allow for descriptive claims such as “Processed in the USA”
- Fall 2022 – consumer survey conducted

# Agricultural Marketing Service

- Domestic Origin Policy
- Bioengineered
  - September 13, 2022 – District Judge remanded the text message disclosure option back to AMS with vacatur to reconsider.

# Prop 12 and Q3

## California and Massachusetts

- Both are fully in effect for veal and eggs
- Both have delayed enforcement for pork
  - through two different vehicles
  - dependent on SCOTUS decision – by end of June 2023



This is not about gestation crates or even animal welfare.

**This is something everyone in the food industry, everyone in manufacturing, should be watching.**

# **Labeling Regulatory Policy**

Current State of Play

# Policy Issues

- COVID-19
- Food and Drug Administration
- Federal Trade Commission
- State Labeling Trends

# Food Regulatory Agencies

- Food Safety and Inspection Service ([FSIS](#))
    - Meat, poultry, siluriformes, and egg products
  - Food and Drug Administration ([FDA](#))
    - All other human and animal foods, including food contact materials, ingredients, *etc.*
- \* *FSIS and FDA signed an [agreement](#) regarding responsibility to products resulting from animal cell culture technology*

**COVID-19**

# COVID-19: National Emergency Declaration

- In February, Executive Office of the President issued an Administrative Order extending the national emergency for the COVID-19 pandemic past March 1.
- In the Order, President Biden indicated his anticipation to terminate the COVID-19 National Emergency on May 11, 2023.

# **White House Conference on Hunger, Nutrition**

# White House Conference on Hunger, Nutrition (September 2022)

- Launching point for the [\*Biden-Harris Administration National Strategy on Hunger, Nutrition, And Health\*](#) (September 2022). Among many initiatives, the Strategy directs FDA
  - to study and propose a front-of-package labeling system,
  - ensure FDA is funded to prioritize its nutrition and labeling work,
  - address marketing of unhealthy foods,
  - among other recommendations.

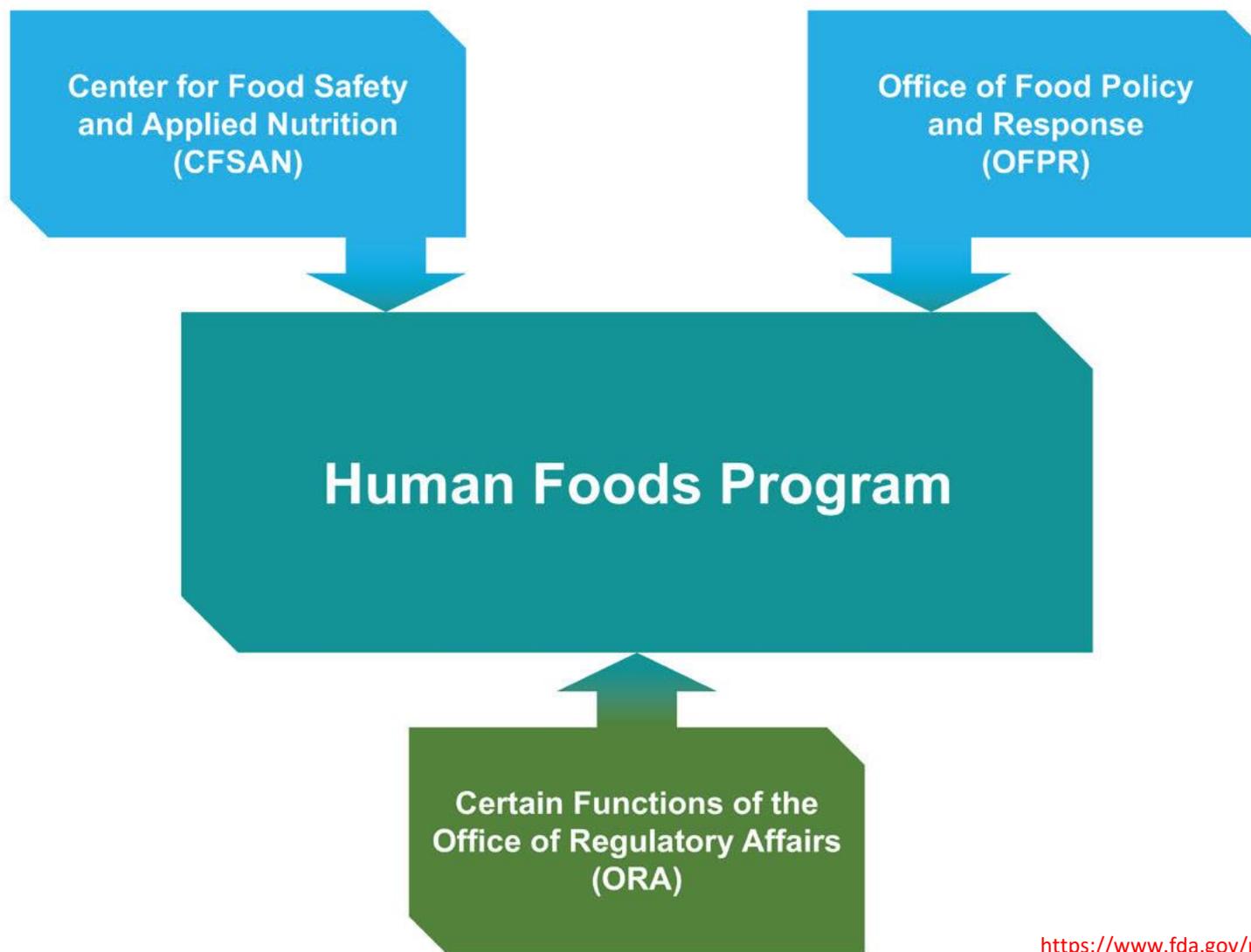
# **Food and Drug Administration**

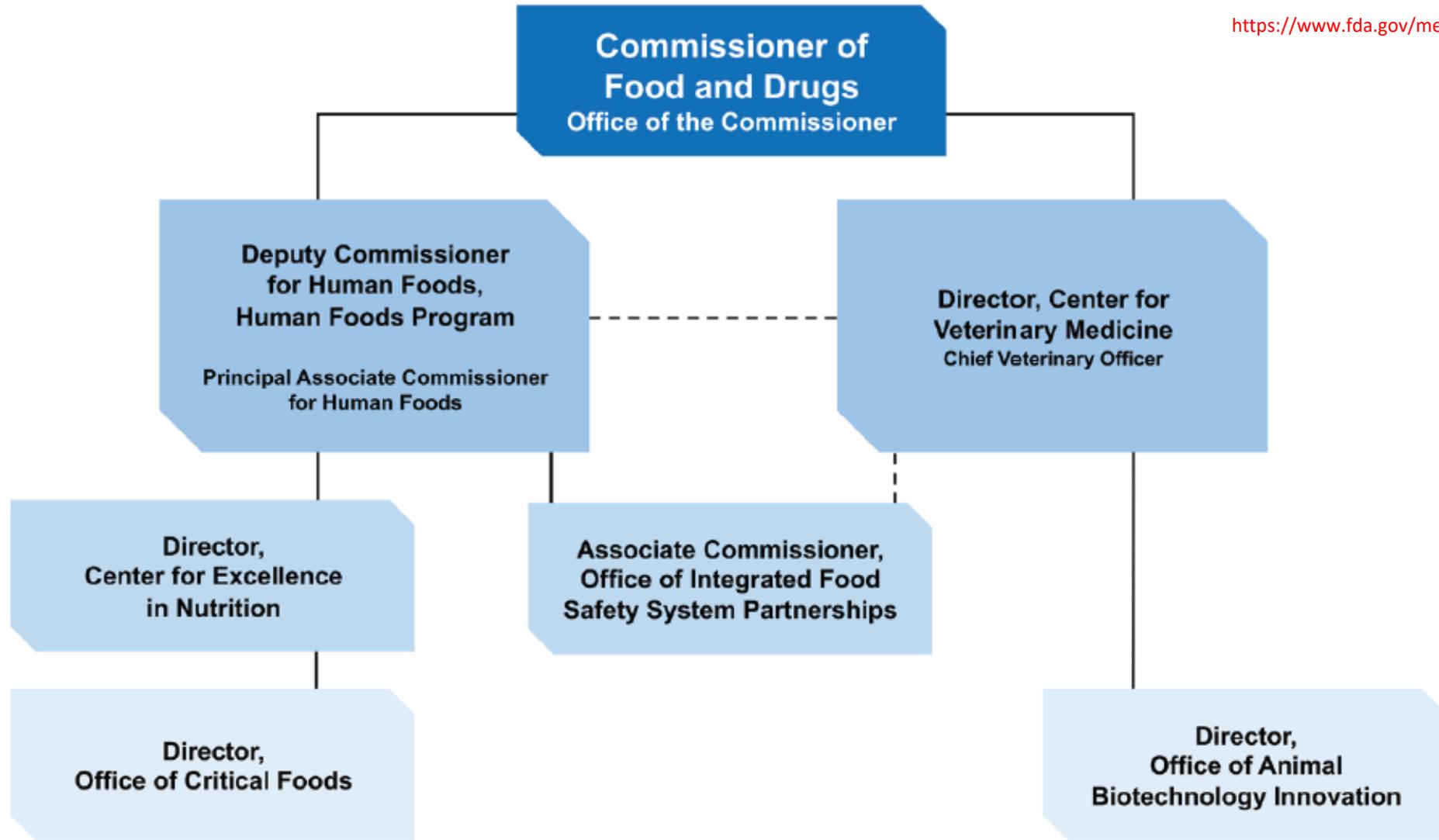
# FDA Organizational Update

- FDA remains under scrutiny ineffectiveness in timely protection of public health and underwent an external review.
- The review found FDA's organizational food program structure is dysfunctional and there is no clear leader or decision maker.

<https://reaganudall.org/operational-evaluation-fdas-human-foods-programs>

- On January 31, FDA outlined the agency's new vision for the Human Foods Program





————— proposed direct reporting relationship

- - - - - proposed matrix relationship with clearly defined roles and decision rights

# Uniform Compliance Date

- January 1, 2026, is the uniform compliance date for those food labeling regulations finalized and published on or after January 1, 2023, and on or before December 31, 2024.
  - Manufacturers to update and comply with new labeling rules as soon as feasible,
  - The date is meant to account for the time it may take to update products and labels to conform to the new requirements

# Sesame

- In April 2021, The FASTER Act was passed, which designated sesame as the ninth major food allergen.
- January 1, 2023, FDA-regulated foods must declare sesame on the label (unless exempted) or be considered misbranded under FD&C Act.



# “Healthy”

- On September 29, FDA published a [proposed rule](#) updating the definition for the implied nutrient content claim “healthy” in 21 C.F.R. § 101.65(d).
  - Aligns with current science and policy.
  - Took a food group approach - contain a certain, meaningful amount of food from at least one of the food groups or subgroups (e.g., fruit, vegetable, dairy, etc.) recommended by the *Dietary Guidelines*.
    - Specific limits for certain nutrients, such as saturated fat, sodium, and added sugars. Threshold for limits is based on a percent of the Daily Value (DV) for the nutrient and varies depending on the food and food group.
    - Written records to verify that the foods meet the food group equivalent requirements, where the food group equivalent is not apparent from the label, has been proposed for two years after the food is introduced into interstate commerce.

# Front-of-Package Labeling

- FDA directed within Action plan to develop a FOP System, which is consistent with previous public commitments that consumers can use to quickly and easily identify foods that are part of a healthy eating pattern.
  - FDA has begun to [conduct research](#) on a symbol that industry can voluntarily use to label food products that meet the proposed “healthy” definition.
- In December 2022, a congressional letter was sent to FDA seeking clarity on their progress in developing a front-of-package labeling system and whether rulemaking is being considered. FDA was asked to respond by January 20.
  - National schemes are already implemented in Mexico, Canada, among other countries, and being considered by the EU.

# Modernizing Food Standards

- As part of FDA's [Nutrition Innovation Strategy](#), changes to food standards to better reflect today's marketplace are being considered.
  - This could impact how plant-based foods are labeled.
- Yesterday, FDA/FSIS withdrew their Proposed Rule on [Food Standards; General Principles and Food Standards Modernization](#).
  - Reconsidering how best to approach general principles and food standards modernization to ensure any future revised general principles are consistent with the relevant Acts.
  - This proposal was proposed in 2005 and had two comment periods (2005 and 2020).

# FDA's New Era of Smarter Food Safety



- Tech-enabled End-to-End Traceability
- Expanding Tools for Prevention and Outbreak Response
- New Business Models and Retail Modernization
- Food Safety Culture

# **Federal Trade Commission**

# ‘Green Guides’ for the Use of Environmental Marketing Claims

- Provide guidance on environmental marketing claims, including how consumers are likely to interpret particular claims and how marketers can substantiate these claims to avoid deceiving consumers under Section 5 of the FTC Act.
  - The Green Guides were first issued in 1992 and were revised in 1996, 1998, and 2012.
- In late December 2022, the FTC announced their intent to review the [\*Guides for the Use of Environmental Marketing Claims\*](#) (Green Guides) for effectiveness and relevancy.
  - A stakeholder comment period through April 24 was opened.
  - Commissioners are expecting stakeholders to provide consumer data to support recommendations.

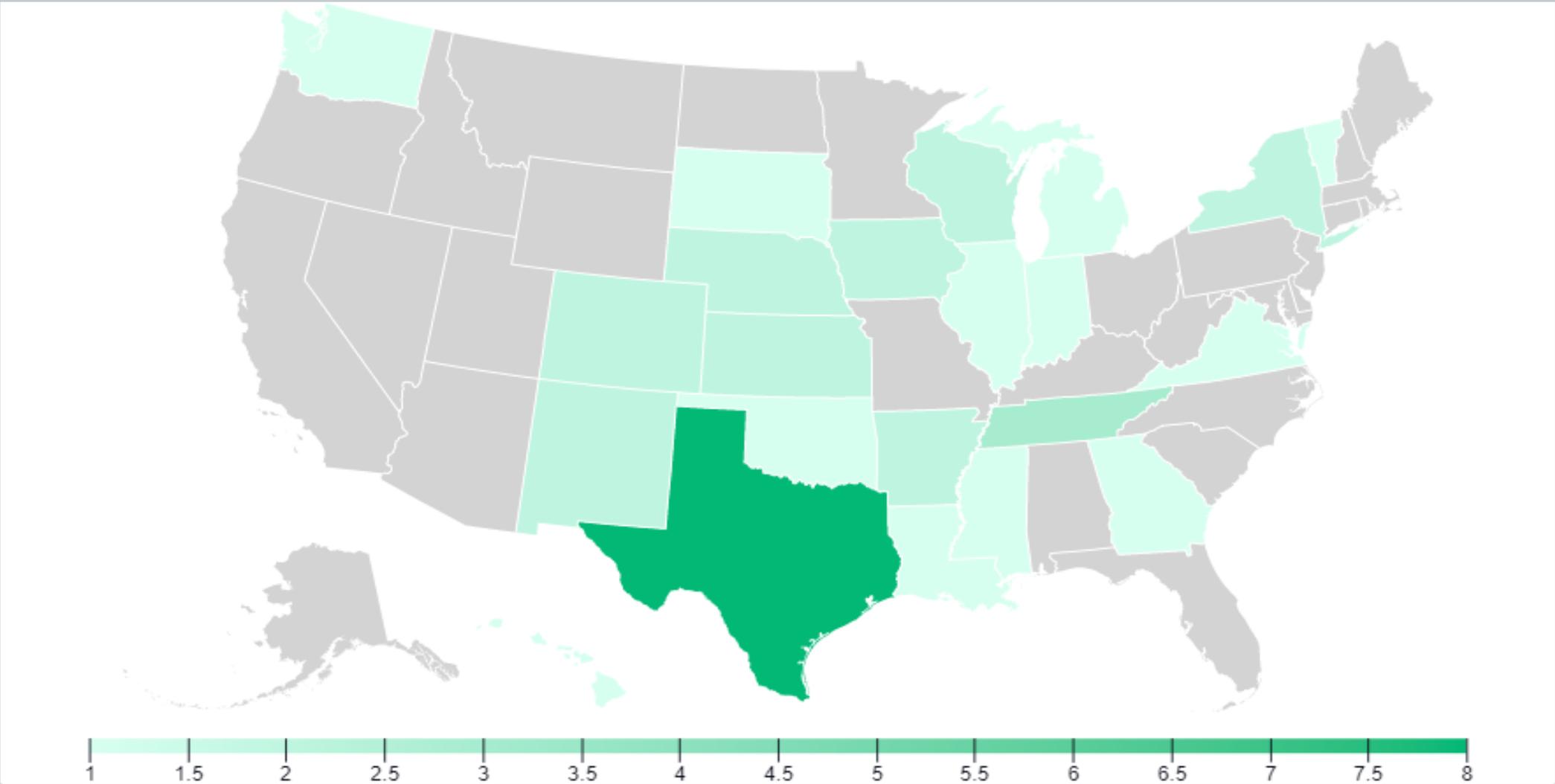
# ‘Green Guides’ for the Use of Environmental Marketing Claims

- Seeking stakeholder comment on:
  - continuing need for the guides;
  - economic impact;
  - their effect on the accuracy of various environmental claims and their interaction with other environmental marketing regulations
- Seeking information on consumer perception evidence of environmental claims, including those not in the guides currently.
  - Carbon Offsets and Climate Change Claims, Term “Recyclable”, Term “Recycled Content” and
  - Thoughts on if other guidance is needed on “compostable”, “degradable”, “ozone-friendly”, “organic”, “sustainability, terms regarding energy use and efficiency, among others.

# **State Labeling Trends**

# State Activity

Plant-Based Labeling 2019 to Present





**United States  
Of Patchwork  
Regulations**

An aerial, high-angle photograph of a dense urban landscape, likely a major financial hub. The image is characterized by a vast number of skyscrapers and high-rise buildings, many with glass facades reflecting the sky. The city is viewed from a high vantage point, looking down. In the center of the image, there is a large, horizontal band of white haze or fog that obscures the buildings beneath it, creating a sense of depth and mystery. The overall color palette is dominated by the greys and blues of the buildings and the white of the haze, with some warmer tones from the sky and distant structures.

**Questions?**