AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Recent Developments in Herbal Products Labeling

Steven Shapiro
Of Counsel
Rivkin Radler LLP

Jenny K. Singh
Associate
Steptoe

Ashish Talati
Member
Talati Law Firm PLLC

Robert Marriott
Director of Regulatory Affairs
AHPA

February 26, 2025

Welcome!

- Materials shown or provided in this webinar are copyrighted property of the American Herbal Products Association (AHPA) and may not be reproduced without AHPA's express written consent. Information presented in this webinar does not constitute legal advice or substitute for the advice of counsel. Attendees seeking legal advice on any subject addressed during this webinar should consult their own counsel. The comments and views expressed by the panelists are their own and do not necessarily reflect the opinions, views, or positions of AHPA. AHPA does not make any warranties, express or implied, statutory or otherwise, regarding the content of this webinar. AHPA is not responsible for the accuracy of any information presented in this webinar and assumes no liability for attendee reliance on the information provided. AHPA does not permit the use of tools for recording, transcribing, or summarizing AHPA events or meetings. For certain events, AHPA makes available on-demand recordings for the convenience of attendees. Any attendees requiring an accommodation should contact Melissa Do at mdo@ahpa.org or (301) 588-1171 ext. 104.

Recent Developments in Herbal Products Labeling
American Herbal Products Association

Food Allergen Labeling and Consumer Protection Act

Steven Shapiro, Of Counsel

212-455-9542

Steven.Shapiro@rivkin.com

RIVKIN RADLER LLP
ATTORNEYS AT LAW

Disclaimer

- This presentation consists of general information about FDA's allergen labeling requirements. It is not intended to give specific legal advice, nor does it create an attorney-client relationship.
- Due to the seriousness of the need to properly disclose major allergens on food and dietary supplement labels, the information provided may not adequately address every situation. Changes in the law or FDA's interpretation of the law could make parts of this presentation obsolete in the future.
- This information is provided with the understanding that the FDA 2025 allergen guidance should be read in its entirety and that if specific legal advice is required the services of a competent attorney should be sought.

RIVKIN RADLER LLP
ATTORNEYS AT LAW

Allergan Labeling Laws

- The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282)
  - Requires disclosure of “major allergens”
    - Intentionally added ingredients, not potential cross contact
- Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) (Public Law 117-11)
  - Adds sesame to the list of “major allergens”
- Final Guidance -- Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry – January 2025

What Must Comply with Allergen Labelling?

- All packaged foods regulated by FDA, including dietary supplements
  - applies to bulk containers for further processing, labeling, or repacking between manufacturers, repackers, or distributors
- Does not apply to pet food or animal feed, OTC drugs, cosmetics, or household cleaning products.
- Does not apply to most meat, poultry, catfish, and certain processed egg products (regulated by USDA)
  - USDA requires ingredient labeling and encourages voluntary allergen statements
- Does not apply to alcohol products regulated by the Alcohol and Tobacco Tax and Trade Bureau

Major Food Allergens

- **Foods**
  - Milk
  - Peanuts
  - Wheat
  - Soybeans
  - Sesame (added January 1, 2023)
- **Food Groups (must identify type or species)**
  - Fish (e.g., bass, flounder, cod)
  - Crustacean shellfish (e.g., crab, lobster, shrimp)
  - Tree nuts (e.g., almonds, walnuts, pecans)

Other Allergens

- There are over 160 other foods that have been reported to cause allergic reaction
  - Although sensitive individuals may react to other foods, they are not required to list food sources under this law **and are excluded from "Contains" statements**
- Guidance for FDA Staff and Interested Parties: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act – January 2025
- Gluten – not a major allergen
  - not required to be disclosed on the label
  - "Gluten Free" claims – are permitted pursuant to 21 CFR 101.91
    - FDA limit 20 ppm and other requirements

Exemptions and Thresholds

- Exemptions
  - Highly refined oils, which are intended to signify refined, bleached, deodorized oils, that are derived from major food allergens are exempt from allergen labeling
    - The source of all oils (whether highly refined or not) must be included as part of the common or usual name of the oil in the ingredient list (such as “soybean oil”)
  - A food ingredient that is exempt under paragraph (6) or (7) of section 343(w) of this title (petitions and notifications)
- Thresholds
  - FALCPA does not require FDA to establish a threshold level for any food allergen.
    - None established

Milk – Definition Change

- Under FALCPA, FDA now considers “milk” as milk from domesticated cows, goats, sheep, or other ruminants (hoofed mammals with a four chambered stomach that digest plant matter through fermentation).
  - Milk from ruminant animals other than cows, must be declared in the ingredient list by common or usual name, such as “goat milk”.
  - For food allergen labeling purposes, milk and milk ingredients from animals **other than cows** should also include the name of the animal source, such as “goat milk” and “whey (goat milk)” in the ingredient list or “Contains goat milk” in a separate “Contains” statement, or both.

Eggs – Definition Change

- Under FALCPA, FDA now considers “eggs” as eggs from domesticated chickens, ducks, geese, quail, and other fowl
  - Eggs from birds other than chickens, when used as an ingredient, must be declared in the ingredient list by common or usual name, such as “duck egg”.
  - For food allergen labeling purposes, egg and egg ingredients from birds **other than chickens** should also include the name of the bird source, such as “duck egg” and “ovalbumin (duck egg)” in the ingredient list or “Contains duck egg” in a separate “Contains” statement, or both.

“Species” of Fish or Crustacean Shellfish

- Ingredient list should be the market or common name provided in FDA’s Seafood List as the “species” of fish or Crustacean shellfish.
  - For the “Contains” statement, in addition to one of these names being used, manufacturers may use the generic name, e.g., “salmon” for chum salmon or “flounder” for tropical flounder.
    - FDA interprets “fish” as • Jawless fish, such as hagfish and lampreys • Bony fish, such as trout, flounder, bass, salmon, tilapia, cod, mackerel, tuna, and grouper • Cartilaginous fish, such as shark, rays, and skates
  - Crustacean Shellfish are major allergens – (e.g., crabs, lobster, shrimp)
  - Mollusks are **NOT** major allergens (e.g., clams, oysters, mussels, snails, octopus)

“Type” of Tree Nut – Definition Change

- Only the tree nuts listed in Table 1 of the new guidance are “major food allergens” and may be included in a “Contains” statement
  - those tree nuts for which a “robust body of scientific evidence exists”
  - No longer includes (among others) – Butternut, Coconut, Gingko Nut, Kola Nut, Lichee Nut, or Shea Nut
- Are other parts of a tree nut plant major allergens?
  - It depends on whether “proteins from that major food allergen” is present

Common or usual name	Scientific name (Family name is identified in parentheses.)
Almond	*Prunus dulcis* (Mill.) D.A. Webb (Rosaceae)
Black walnut	*Juglans nigra* L. (Juglandaceae)
Brazil nut	*Bertholletia excelsa* Humb. & Bonpl. (Lecythidaceae)
California walnut	*Juglans californica* S. Watson (Juglandaceae)
Cashew	*Anacardium occidentale* L. (Anacardiaceae)
Filbert/Hazelnut	*Corylus* spp. (Betulaceae)
Heartnut/Japanese walnut	*Juglans ailantifolia* Carriere var. *cordiformis* (Makino) Rehder (Juglandaceae)
Macadamia nut/Bush nut	*Macadamia* spp. (Proteaceae)
Pecan	*Carya illinoinensis* (Wangenh.) K. Koch (Juglandaceae)
Pine nut/Pinon nut	*Pinus spp.* (Pineaceae)
Pistachio	*Pistacia vera L.* (Anacardiaceae)
Walnut (English, Persian)	*Juglans regia L.* (Juglandaceae)

Wheat

- The term “wheat” means any species in the genus Triticum.
  - Includes – common wheat (Triticum aestivum L.), durum wheat (Triticum durum Desf.), club wheat (Triticum compactum Host.), spelt (Triticum spelta L.), semolina (Triticum durum Desf.), Einkorn (Triticum monococcum L. subsp. monococcum), emmer (Triticum turgidum L. subsp. dicoccon (Schrank) Thell.), Khorasan (Triticum polonicum L.), and triticale (x Triticosecale ssp. Wittm.).

Soybean, Peanut and Sesame

- “Soybean,” “soy,” and “soya” are reasonable synonyms for the common or usual name “soybeans”
- “Peanut” / “Peanuts”
- “Sesame” – if not declared as a separate ingredient must be declared in a “Contains” statement or in a parenthetical after the collective term “spice” or “spices” in the ingredient list, i.e., “Contains sesame” or “spices (sesame).”

On the Label -- Option 1 -- In the Ingredient Statement

- Disclose the presence of all major allergens in the statement of ingredients
  - Cocoa Crispers Bar
    - **Ingredients:** Milk Chocolate (Sugar, Milk, Cocoa Butter, Chocolate, Vanilla), Corn Syrup, Whey, Cocoa Powder, Crisped Rice (Rice, Sugar, Salt, Malt), Flour (Wheat), Soy Protein, Ovalbumin (Duck Egg), Natural Flavor (Peanut)
    - **Ingredients:** Milk Chocolate (Sugar, Milk, Cocoa Butter, Chocolate, Vanilla), Corn Syrup, Whey, Cocoa Powder, Crisped Rice (Rice, Sugar, Salt, Malt), Wheat Flour, Soy Protein, Ovalbumin (Duck Egg), Natural Peanut Flavor
- If a Contains statement were used
    - Contains: Milk, Wheat, Soy, Duck Egg, Peanuts

On the Label -- Option 2 -- “Contains” Statement

- The word “Contains” with a capital “C” must be the first word used to begin a “Contains” statement. (The use of bolded text and punctuation within a “Contains” statement is optional.)
  - Immediately after or next to the list of ingredients
  - Same type size
  - Additional wording may be used for a “Contains” statement to more accurately describe the presence of major food allergens
- If included on a food label, the “Contains” statement **must identify the names of ALL major food allergens that either are in the food or are contained in ingredients of the food.**

Dietary Supplement Labeling

Supplement Facts

Serving Size 1 Scoop (35.7g)
Servings Per Container About 25

Amount Per Scoop	% Daily Value
Calories 130	
Total Fat 1 g	1%*
Saturated Fat 0.5 g	3%*
Total Carbohydrate 4 g	1%*
Dietary Fiber 1 g	4%*
Total Sugars 1 g	†
Protein 26 g	
Calcium 134 mg	10%
Iron 1.6 mg	9%
Sodium 180 mg	8%
Potassium 337 mg	7%
Whey Protein Isolate (Milk) 29 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other Ingredients: Cocoa Powder (Processed with Alkali), Erythritol, Natural Flavors, Sea Salt (Sodium Chloride), Gum Blend (Guar Gum, Gum Acacia, Xanthan Gum), and Rebaudioside A.

Supplement Facts

Serving Size 1 Scoop (35.7g)
Servings Per Container About 25

Amount Per Scoop	% Daily Value
Calories 130	
Total Fat 1 g	1%*
Saturated Fat 0.5 g	3%*
Total Carbohydrate 4 g	1%*
Dietary Fiber 1 g	4%*
Total Sugars 1 g	†
Protein 26 g	
Calcium 134 mg	10%
Iron 1.6 mg	9%
Sodium 180 mg	8%
Potassium 337 mg	7%

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Whey Protein Isolate (Milk), Cocoa Powder (Processed with Alkali), Erythritol, Natural Flavors, Sea Salt (Sodium Chloride), Gum Blend (Guar Gum, Gum Acacia, Xanthan Gum), and Rebaudioside A.

Supplement Facts

Serving Size 1 Scoop (35.7g)
Servings Per Container About 25

Amount Per Scoop	% Daily Value
Calories 130	
Total Fat 1 g	1%*
Saturated Fat 0.5 g	3%*
Total Carbohydrate 4 g	1%*
Dietary Fiber 1 g	4%*
Total Sugars 1 g	†
Protein 26 g	
Calcium 134 mg	10%
Iron 1.6 mg	9%
Sodium 180 mg	8%
Potassium 337 mg	7%
Whey Protein Isolate 29 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other Ingredients: Cocoa Powder (Processed with Alkali), Erythritol, Natural Flavors, Sea Salt (Sodium Chloride), Gum Blend (Guar Gum, Gum Acacia, Xanthan Gum), and Rebaudioside A.

Contains Milk (Whey)

RIVKIN RADLER LLP
ATTORNEYS AT LAW

Spices, Favorings, Certain Colors, Incidental Additives and Processing Aids

- Spice, flavorings and colors
  - Must declare major allergens -- parenthetically after the term “spice(s)” in the ingredient list, or in a separate “Contains” statement, or both.
    - “Spices (sesame)” or “Contains Sesame”
    - “Natural Flavor (Peanut)” or “Natural Peanut Flavor” or “Contains Peanut”
- Incidental additives, including processing aids, are ingredients added to a food that are exempt from being declared in the ingredient list (21 CFR 101.100(a)(3)).
  - NOT exempt from the food allergen labeling requirements
  - If not declared as an ingredient must appear in “Contains” statement

Individual Units within a Multiunit Package

- If labeled not for individual or retail sale, the unit containers in a multiunit food package are exempt from certain labeling requirements -- including an ingredient statement
  - However, such foods are not exempt from allergen labeling requirements.
    - If the food is or contains a major food allergen, a “Contains” statement must be used on each of the inner labels.
    - Declared near statement of identity, absent ingredient list
- No labeling is needed, including allergen labeling, if the individual unit is an unlabeled inner sleeve intended solely for protection of the product, such as sleeves of crackers, and does not contain any written, printed, or graphic matter.

“Free” Claims

- Voluntary statements providing information that certain allergens are absent from the product (e.g., “allergen-free” claim) are permitted
  - Must be truthful and not misleading
- FDA would expect there to be no milk allergen in the product, including unintended milk allergen presence due to cross-contact.
  - Could be consumed by an allergic person with confidence
- A product with an allergen-free claim should not have an advisory statement “may contain” statement for the same allergen.

CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-Contact – Guidance For FDA Staff

- Voluntary use of allergen advisory statements to alert consumers to the possible presence of major food allergens due to cross-contact.
  - Examples -- “may contain [allergen],” or “produced in a facility that also uses [allergen].”
- Not a substitute for adherence to current good manufacturing practices and/or food allergen preventive controls.
- FDA may deem a product adulterated when there is inadequate allergen cross contact controls, despite advisory statement
- Any allergen advisory statement must be truthful and not misleading

Petitions and Notifications

- **Petitions under Section 343(w)(6) for Exemptions from Food Allergen Labeling**
  - petition that provides scientific evidence (including the analytical method) that demonstrates that an ingredient, does not cause an allergenic response that poses a risk to human health
    - Burden on petitioner
    - 180 days for FDA to approve or deny the petition.
- **Notifications under Section 343(w)(7) for Exemptions from Food Allergen Labeling**
  - notification containing scientific evidence demonstrating that an ingredient "does not contain allergenic protein."
    - 90 days for FDA to object to a notification

Need To Relabel?

- In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in FDA guidances means that something is suggested or recommended, but not required.

Steven Shapiro, Esq.
Of Counsel
212-455-9542
Steven.Shapiro@rivkin.com

RIVKIN RADLER LLP
ATTORNEYS AT LAW

TALATI

FDA's Final Rule on "Healthy" label claims

Ashish Talati
Member
Talati Law Firm

TALATI

FDA's Revised "Healthy" Label Definition

- Published: December 27, 2024
- The Nutrition Labeling and Education Act (1990) allows FDA to regulate nutrient content claims.
  - Healthy is an implied nutrient content claim -
    - "Suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, where there is also implied or explicit information about the nutrition content of the food".
  - **Includes derivative terms**: "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness".

TALATI

Why the update?

- Align food labeling with **current nutrition science** & the Dietary Guidelines for Americans, 2020-2025.
- **Previous Limitations:**
  - 1994 rule **excluded** nutrient-rich foods like **salmon** due to fat content.
  - Allowed some foods high in **added sugars** to carry the "healthy" claim.
- **Impact:**
  - Helps consumers identify foods that support a balanced diet.
  - Ensures food labels are **accurate, truthful, and not misleading**.
  - Encourages healthier food choices.

TALATI

Compliance & Record-keeping

- Effective date: April 28, 2025
- Compliance date: Feb 25, 2028 (Manufacturers may adopt earlier or continue to use the original definition of “healthy’’ until the compliance date)
- **Record Keeping -** Make and keep written records to verify that the food meets the FGE requirements where food group content **is not clear from the label**.
- Retention period: At least 2 years after product enters interstate commerce.
- FDA Inspection: Records must be available upon request.
- Beyond Packaging:
  - Fresh foods (e.g., fruits & vegetables) can display the claim via signage or store materials instead of packaging.

TALATI

Food Group Equivalents (FGE)

- FDA measures nutrient value in portion sizes called Food Group Equivalents (FGE).
- Serving size basis: Reference Amount Customarily Consumed (RACC) or per 50 gram if RACC of 50 g or less
- Criteria for "healthy" claim depends on:
  - Type of food product (individual vs. mixed products, main dishes, meals).
  - Required amounts from food groups.
  - Limits on sugar, sodium, and saturated fat.

TALATI

Criteria for “Healthy” Nutrient Content Claim

- **Food must contain** a **minimum amount** from at least one **food group** recommended by the **Dietary Guidelines for Americans**:
  - **Fruits | Vegetables | Grains**
  - **Dairy | Protein Foods | Oils**

- **Must meet limits for:**
  - ⚠️ **Added Sugars**
  - ⚠️ **Saturated Fat**
  - ⚠️ **Sodium**

TALATI

Automatically Qualifying Foods

No Added Ingredients Except Water – These foods meet the **"healthy"** claim based on their nutrient profile when sold individually or mixed products comprised of:

- ✅ **Vegetables & Fruits**
- ✅ **Whole Grains**
- ✅ **Fat-Free & Low-Fat Dairy**
- ✅ **Lean Meat & Seafood**
- ✅ **Eggs**
- ✅ **Beans, Peas & Lentils**
- ✅ **Nuts & Seeds**
- ✅ **Water, Tea & Coffee (<5 calories per serving and RACC)**

TALATI

Water, Tea, and Coffee

- All water, tea (of *Camellia sinensis* specifically), and coffee with less than 5 calories per RACC and per labeled serving can make the claim.
- Includes:
  - ✓Carbonated or noncarbonated water
  - ✓Coffee, and tea, containing non-caloric ingredients such as flavors, no- or low-calorie sweeteners, vitamins, and minerals but no added caffeine

Note: Only tea derived from *Camellia sinensis* — and not to herbal tea or herbal infusions.

TALATI

Individual Foods

Vegetable

- 1/2 cup equivalent
- no more than 2% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 5%

Fruit

- 1/2 cup equivalent
- no more than 2% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 5%

Grain

- 3/4 oz equivalent whole grain
- no more than 10% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 5%

Dairy

- 2/3 cup equivalent
- no more than 5% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 10%

*Plant-based dairy products labeled and marketed as dairy alternatives will be evaluated against the dairy food group

TALATI

Proteins

Game Meats

- 1 1/2 oz. equivalent
- no more than 2% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 10%

Seafood

- 1 oz. equivalent
- no more than 2% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 5%, EXCLUDING *

Egg

- 1 oz equivalent
- no more than 2% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 10%

Beans, peas and lentils

- 1 oz equivalent
- no more than 2% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 5%

Nuts, seeds and soy products

- 1 oz equivalent
- no more than 2% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- saturated fat content no greater than 5%, EXCLUDING**

*excluding saturated fat inherent in seafood.

**excluding saturated fat inherent in nuts, seeds, and soybeans.

TALATI

Oils

Oil

- containing no added sugars or sodium
- no more than 20% of total fat is saturated fat

Oil-based spreads whose fats come solely from oil

- containing no added sugars
- no more than 10% of the daily value of sodium
- no more than 20 % of total fat is saturated fat

Oil-based dressing containing at least 30% oil*

- no more than 2% of the daily value of added sugars
- no more than 10% of the daily value of sodium
- No more than 20% of total fat is saturated fat

TALATI

Mixed Products

- 1 total FGE with no less than ¼ FGE from at least two food groups.
- Added sugar ≤ 10% of daily value.
- Sodium ≤ 15% of daily value.
- Saturated fat ≤ 10% of daily value (excluding inherent fats from seafood, nuts, and seeds).

TALATI

Main Dish Products

- 2 total Food Group Equivalents (½ from at least two groups).
- Added sugar ≤ 15% of daily value.
- Sodium ≤ 20% of daily value.
- Saturated fat ≤ 15% of daily value (excluding inherent fats).¼ Food Group Equivalent from at least two food groups.

TALATI

Meal Products:

- 3 total Food Group Equivalents (½ from at least three groups).
- Added sugar ≤ 20% of daily value.
- Sodium ≤ 30% of daily value.
- Saturated fat ≤ 20% of daily value (excluding inherent fats).

TALATI

Dietary Supplements/Herbal Products

- Dietary supplements are not exempt from the “healthy” nutrient content requirements.
- Structure function claims can use “healthy” if no nutritional context.
- Herbs or spices may qualify as vegetables for the purpose of calculating FGE for the use of “healthy” claims.
- Dried or other powdered fruits and vegetables can be considered in FGE calculations if the powders are essentially the dried and ground forms of the original whole food.

TALATI

Nutritional Context

- Not all claims that use the term “healthy’’ are subject to requirements of the rule.
- “Healthy” must be used in a nutritional context for the “healthy” criteria to apply. For example - when “healthy’’ is used and other information, such as other claims, images, or vignettes, about the nutrition content of the food is also present somewhere on the labeling.
- Or presented in a context that explicitly or implicitly suggests that the food has a particular nutrient profile.
- Information that puts “healthy’’ into a nutritional context need not be immediately adjacent to the implied nutrient content claim.
- FDA will apply a flexible, case-by case approach that considers the overall content of the label and labeling when determining the “healthy’’ claim in a nutritional context.

TALATI

Resources

- Dietary Guidelines, 2020-2025 available at
  - ➢https://www.dietaryguidelines.gov
- The USDA Food Patterns Equivalents Database (FPED)
  - ➢https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fped-data-tables/
- FDA plans to have a webinar on the updated “Healthy” claim soon.
  - ➢https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-updated-healthy-claim-02202025

TALATI

Thank you!

646-904-8076
ashish@talati-law.com
Talati-law.com

Steptoe

www.steptoe.com

www.linkedin.com/company/steptoe-&-johnson-llp

@SteptoeLLP

For more information about Steptoe, the partners and their qualifications,
see **www.steptoe.com.**

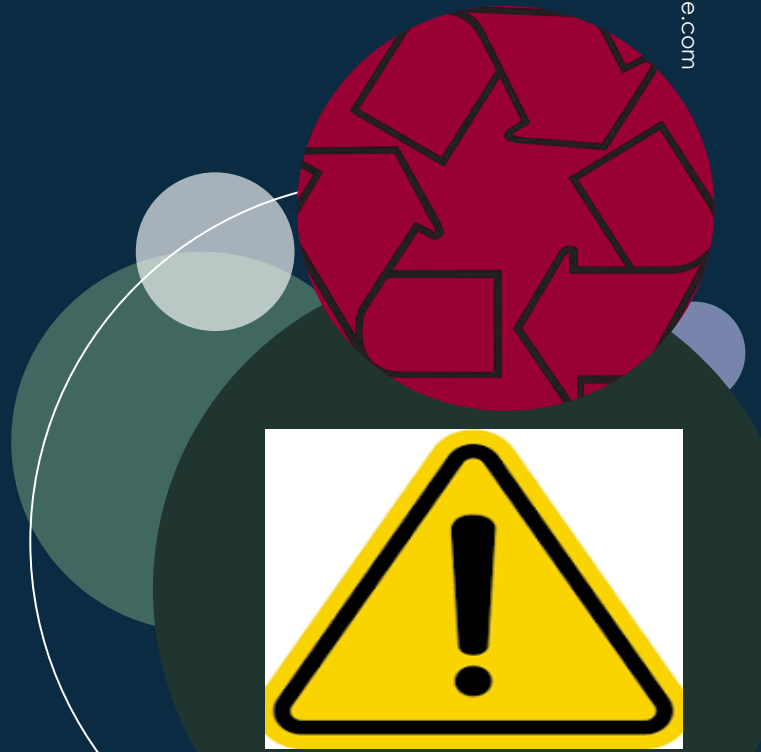
Where case studies are included, results achieved do not guarantee similar outcomes for other clients. Attorney advertising. Images of people may feature current or former lawyers and employees at Steptoe or models not connected with the firm.

Steptoe

www.steptoe.com

Recent Developments in Herbal Products Labeling:

Recyclability under California's Framework; and the New Prop 65 "Short Form" Warnings



Jenny K. Singh
AHPA Webinar
February 26, 2025

Jennifer Karpinski Singh
Associate
San Francisco, CA
+1 415 365 6722
jsingh@steptoe.com

- Jenny is trial counsel in Steptoe's San Francisco office.
- She provides counsel to clients on how to minimize risk, and on best practices to ensure compliance related to the regulation of consumer and food products.
- Jenny has over 15 years of experience in the fields of product liability, chemical law, and class action defense for a diverse array of clients, large and small, including manufacturers, distributors and retailers in the chemical, food, cosmetic, dietary supplement and drug industries.
- Jenny recently achieved a 2023 defense verdict after a three-week Prop 65 trial involving allegations of lead in rice; and secured a 2024 dismissal of a Prop 65 food case during trial.

Roadmap

Part One

What is Proposition 65?

P65 is a “Right to Know” Warnings Law

It only Applies to Products Sold in or to California

THE KEY LANGUAGE:

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

CA Health & Safety Code § 25249.6.

Prop 65 Affects Almost Everything & Everywhere

Building & Home Improvement

Children's Products

Cleaning Clothing Cookware

Cosmetics & Personal Care

Electronics

Furniture & Fixtures

Food

Food Packaging

Product Packaging

Food & Supplements

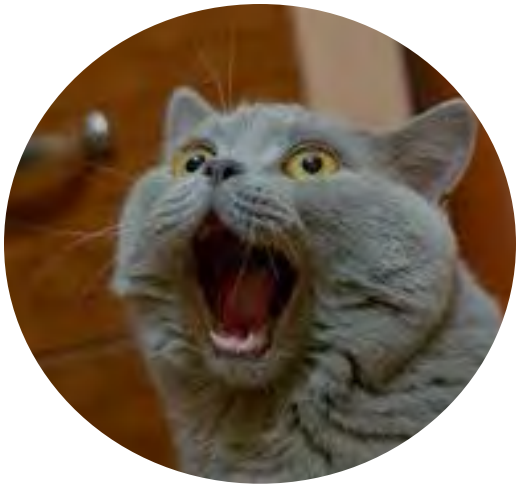
Building Materials

Automobiles

Shopping Bags

Gas stations

Hotel lobbies



The Prop 65 "List"

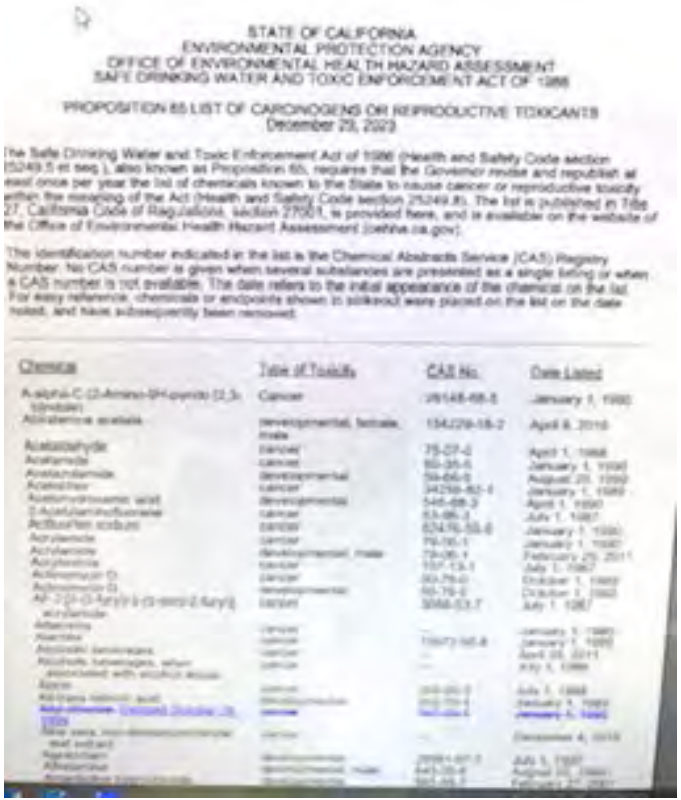
Includes over 900 different chemicals

Some listed as known to cause reproductive harm

Some listed as known to cause cancer.

Some listed as known to cause both.

State updates list regularly



STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

PROPOSITION 65 LIST OF CARCINOGENS OR REPRODUCTIVE TOXICANTS
December 29, 2023

Chemical	Type of Toxicity	CAS No.	Date Listed
A-alpha-C (2-Amino-9H-pyrido [2,3-b] indole)	Cancer	[illegible]	January 1, 1990
Abiraterone acetate	developmental, female, male	154229-18-2	April 8, 2016
Acetaldehyde	cancer	75-07-0	April 1, 1988
Acetamide	cancer	60-35-5	January 1, 1990
Acetazolamide	developmental	59-66-5	August 20, 1999
Acetochlor	cancer	34256-82-1	January 1, 1989
Acetohydroxamic acid	developmental	546-88-3	April 1, 1990
2-Acetylaminofluorene	cancer	53-96-3	July 1, 1987
Acifluorfen sodium	cancer	62476-59-9	January 1, 1990
Acrylamide	cancer	79-06-1	January 1, 1990
Acrylonitrile	developmental, male	79-06-1	February 25, 2011
Adriamycin	cancer	23214-92-8	July 1, 1987
Aflatoxins (2)	cancer	1402-68-2	October 1, 1988
Aflatoxins (2)	cancer	1402-68-2	October 1, 1992
AF-2 [2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide]	cancer	3688-53-7	July 1, 1987
Alfentanil	cancer	[illegible]	January 1, 1990
Alkanna	cancer	[illegible]	January 1, 1990
Alcoholic beverages	cancer	[illegible]	April 22, 2011
Alcoholic beverages, when associated with alcohol abuse	cancer	[illegible]	July 1, 1988
Alprazolam	cancer	[illegible]	July 1, 1988
Aristolochic acid	developmental	[illegible]	January 1, 1992
Asbestos [Diagnosed October 19, 1988]	cancer	[illegible]	January 1, 1992
Atrazine [was once part of the mixture]	cancer	[illegible]	December 4, 2015
Azacitidine	developmental, male	[illegible]	July 1, 1992
Azathioprine	developmental, male	[illegible]	August 20, 1999

Cal Health & Safety Code § 25249.8,
22 CCR § 27001

P65 Does Not Require a Product be “Safe”

P65 Does Not Require You to Reformulate Product

- The Prop 65 warning is not based on the safety of a product.
- It is not based on a specific amount of a chemical in a product.
- A product can have a “high” amount of a chemical present and still be Prop 65 compliant
- P65 Does not require redesign or reformulation of products to reduce the level of a chemical present.

Safe Harbor Levels

The state has established levels of acceptable exposure for many chemicals.

Chemicals that are listed as both a reproductive toxicant and a carcinogen may have two safe harbor levels, one for each endpoint.

Exposure in Prop 65 is calculated in micrograms (ug) per day. If your calculation shows that the average exposure to the average consumer falls below the state-set safe harbor, a warning would not technically be required.

- **Example**: for lead, the safe harbor for reproductive harm is 0.5 ug/day. For cancer, the level is 15 ug/day.

Some chemicals are on the List and do not have state-set safe harbor levels.

- **Example:** Three PFAS chemicals are on the List but have no safe harbor level set.

22 CCR §§ 25705, 25709

What is Required to Demonstrate a Prop 65 Violation?

- **Plaintiff must first prove:**
  - A "*knowing and intentional*" exposure
  - Made *without* a "clear and reasonable warning."

- **This means:**

Show a detectible amount of the chemical is present in the product; and

Show no warning was provided on the product and/or on the internet

CA Health and Safety Code § 25249.6

Prop 65 and Penalties

- Separate **liability for all in the chain** – manufacturer, importer, fabricator, packager, distributor and retailer. *(Regs say manufacturer is primarily responsible, but can attempt to shift to retailer)*

- ***Penalties*** *of up to $2,500 per day per violation*

- **Cannot apply to foreign** manufactures and suppliers, meaning the U.S. company in the chain will usually be on the hook.

Guilty Until You Prove Otherwise

- Settling one claim can cost you tens of thousands of dollars (if not more)
- Litigating a case is expensive and carries significant risk
- "Solution" is often to place warnings on products that are actually "safe"
- Customer confusion and lost business
- Expensive/difficult to reformulate product

- ***WHAT CAN YOU DO TO AVOID THIS?***

Prop 65 Warnings Abound

Part Two

Prop 65 Warnings: *Overview*

What Does “Clear and Reasonable” Mean?

- **“…prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, lab.”**

- Technically, you can use any warning language if it meets the above requirement.

- **A compliant warning must be given to the consumer before exposure.**

  For internet and catalogue purchases the warning must appear (or have a hyperlink to the warning) before purchase is complete. The warning must also be on the product/package that is shipped.

- (27 CCR § 25600(f). (emphasis added.).)

“Safe Harbor” Warnings = Clear and Reasonable = Compliant

The state has established “safe harbor” warning language that, if used, is deemed compliant.

The term “safe harbor” in Prop 65 can mean:

Levels of exposure to specific chemicals above which warnings are required.

Warning language – specific wording and presentation the state establishes.

Most companies who choose to place warnings on their products use the safe harbor language, though they can use their own language if it is “clear and reasonable.”

Consumer Products Safe Harbor “Long Form” Warning

1. Black exclamation point in a yellow equilateral triangle with a bold black outline.

2. Where the sign, label or shelf tag for the product is not printed with any yellow, the symbol can be in black and white.

3. The symbol shall be placed to the left of the text of the warning, in a size no smaller than the height of the word “WARNING”.

4. The word “**WARNING:**” or the words “**CA WARNING:**” or “**CALIFORNIA WARNING:**” in all capital letters and bold print.

5. If 1-4 included, then choose one of FOUR OPTIONS – Depends on the chemical or chemicals you seek to warn about.

   Some chemicals are carcinogens, some are reproductive toxicants, and some are both.

   Example: lead is both a carcinogen and a reproductive toxicant.

→ Where a sign or label is used to provide a warning that includes consumer information about a product in a language other than English, the warning must also be provided in that language in addition to English.

22 CCR § 25603

Consumer Products Safe Harbor "Long Form" Warning
⟹ *Is the Chemical a Carcinogen or a Reproductive Toxicant?*

Question: What chemical or chemicals do you want to warn about?

- **IF WARNING FOR ONLY CANCER**

"This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov."

- **IF WARNING FOR ONLY REPRODUCTIVE TOXICITY**

"This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

22 CCR § 25603

Consumer Products Safe Harbor "Long Form" Warning

⟹*Warning for Both a Carcinogen and a Reproductive Toxicant*

TWO OPTIONS IF WARNING FOR **BOTH CANCER AND REPRODUCTIVE TOXICITY**

1 Two separate chemicals - One chemical is a carcinogen and one is a reproductive toxicant

"This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

2 One chemical is both a carcinogen and a reproductive toxicant

"This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

(22 CCR § 25603)

⚠ **WARNING:** This product can expose you to chemicals including Lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov

Part Three

New Short Form Warning Requirements:

Effective January 1, 2028

Consumer Products Safe Harbor "Short Form" Warning
⟹ *Valid Until January 1, 2028*

1. Black exclamation point in a yellow equilateral triangle with a bold black outline. Where the sign, label or shelf tag for the product is not printed using the color yellow, the symbol may be printed in black and white.
2. The symbol shall be placed to the left of the text of the warning, in a size no smaller than the height of the word "WARNING".
3. The word "**WARNING:**" in all capital letters, in bold print.

Question: What chemical or chemicals do you want to warn about?

- "Cancer -- www.P65Warnings.ca.gov."
- "Reproductive Harm --www.P65Warnings.ca.gov."
- "Cancer and Reproductive Harm -- www.P65Warnings.com"

22 CCR § 25603

Consumer Products Safe Harbor "Short-Form" Warning
⟹ Optional Until and Required after ***January 1, 2028***

- 22 CCR 25601 - 25603

The short-form warning will require identification of at least one chemical per endpoint (cancer and reproductive harm) and two options for the text, as follows:

For exposures to listed carcinogens:

- ⚠WARNING: Cancer risk from exposure to [name of chemical]. See www.P65Warnings.ca.gov.

or

- ⚠WARNING: Can expose you to [name of chemical], a carcinogen. See www.P65Warnings.ca.gov.

For exposures to listed reproductive toxicants:

- ⚠WARNING: Risk of reproductive harm from exposure to [name of chemical]. See www.P65Warnings.ca.gov.

or

- ⚠WARNING: Can expose you to [name of chemical], a reproductive toxicant. See www.P65Warnings.ca.gov.

For exposures to both listed carcinogens and reproductive toxicants:

- ⚠WARNING: Risk of cancer from exposure to [name of chemical] and reproductive harm from exposure to [name of chemical]. See www.P65Warnings.ca.gov .

or

- ⚠WARNING: Can expose you to [name of chemical], a carcinogen, and [name of chemical], a reproductive toxicant. See www.P65Warnings.ca.gov.

The Safe Harbor "Short-Form" Warning – *Starting January 1, 2028*

- **The short-form warning can be used regardless of the size of the product package, but:**

  It must be provided in a minimum 6-point font; and

  "Conspicuous" (*i.e.,* "conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use").

Can use any one of these:

- "CALIFORNIA WARNING"
- "CA WARNING"
- "WARNING"

⚠ **WARNING:** Can expose you to formaldehyde, a carcinogen. See www.P65Warnings.ca.gov.

The Safe Harbor "Short-Form" Warning
⟹ *Internet & Catalogue Purchases*

Three options for warnings tied to internet purchases:

1. On the product display page; or

2. A clearly marked hyperlink on the product display page using the words "WARNING" or "CA WARNING" or "CALIFORNIA WARNING," that links to the full warning; or

3. Prominently displayed warning provided prior to completing the purchase ("the warning is not prominently displayed if the purchaser must search for it in the general content of the website"). This would allow for "pop up" warnings and similar approaches that appear to a California consumer prior to completing the transaction.

- Warning must be both on the product and on the webpage.

22 CCR § 25602

The Safe Harbor "Short-Form" Warning – *Starting January 1, 2028* ⟹ *Internet & Catalogue Purchases*

- Website warnings may use the "short-form" if it accompanies the product when sold in brick-and-mortar retail stores.

- 60-day grace period for online retailers to update webpage warnings after receiving a notice of the change from the manufacturer, or after a 60-day notice of violation is received from a plaintiff.

- *For catalogue purchases*, a warning must be in a manner that clearly associates it with the item being purchased. If a short-form warning is being provided on the label the warning provided in the catalog may use the same content.

Warnings - Food

Can use either the long or short-form warnings.

If using the short-form warning for food, the warning does not require the yellow triangle with the exclamation point.

Need to include "/food" after the state's e-mail address www.P65Warnings.ca.gov/food

WARNING: Consuming this product can expose you to lead, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.

CA WARNING: Can expose you to lead, a carcinogen and reproductive toxicant. See www.P65Warnings.ca.gov/food.

Some of the Products/Chemicals Targeted in Recent Prop 65 Claims

December 2024 Proposition 65 Notice of Violation Summary (~394)		
Number of Violations (vs. November)	**Listed Chemicals**	**Types of Products Targeted**
180/198	Heavy metals (lead, cadmium, arsenic)	Food items (granola bars, seafood, chips, ramen, sauces, seeds, mushrooms), dietary supplements/protein powders, brass components, ceramics/glass [28 amendments]
103/61	Diethanolamine/ cocamide diethanolamine	Hand soap, cleanser, foundation, shampoo, shave gels, creams, mascara, lotion [13 amendments]
59/58	Phthalates (DEHP, DINP, DBP)	Tools, pouches/bags/ purses, cases, vinyl grips (kettlebells), hoses [7 amendments]
27/29	PFOA, PFNA	Hats, jackets, snow pants, placemats, tablecloths, umbrellas, body tape/tapes, vegetable stock, milk drinks, shower curtains
13/25	delta-9-tetrahydro-cannabinol, Marijuana smoke	Cannabis products
4/4	Chromium (hexavalent compounds)	Gloves, footwear
4/3	BPA	Canned coconut water, Step heels, teas,
3	Nitrous oxide	Shave gel/foam
	www.prop65madesimple.com	

Part Four

Recyclability Under California's Developing Framework

The interplay between SB 343, SB 54, and FTC's Green Guide

California's "Recyclable /Compostable" Revolution

- By 2032, all non-reusable covered material must be eligible to be labeled "recyclable" or "compostable"
  - Recyclable = SB 343 standards
    - Compostable for plastic means compliance with applicable ASTM standards for commercial composting (e.g., D6400 or D6868) or the OK compost Home certification), and must be USDA NOP allowable organic agricultural input starting 2026
      - Lack of clarity, especially for recyclable, but MUCH of packaging currently in commerce will be totally banned by 2032 unless there is an extreme shift in the current trends

The meaning of “Recyclable” in California

- **CA’s SB 343 was adopted on October 5, 2021 and regulates all things “recyclable”**
  - **Sea-change law that establishes a new standard for recyclable claims**
  - ***Any* recyclable claim is permissible only if**: (1) collected by recycling programs in jurisdictions encompassing at least 60 percent of the state’s population; (2) sorted into defined streams for recycling processes by at least 60 percent of the state’s recycling programs; (3) no components, inks, additives, or labels that prevent them from being recycled per APR Design® Guide; (4) “designed to ensure recyclability”; (5) may not contain certain chemicals identified by California regulations; and (6) not made from plastic or fiber that contains PFAS meeting certain criteria
  - Much higher standard than FTC Green Guide, which does NOT preempt state laws
  - SB 343 requirements tied to *actual collection and repurposing* versus FTC tie to availability

When Does this Go into Effect?

- Effective 18 months after CA finalizes the material characterization study
- Finalization of the current draft study is expected roughly in April of 2025
- Anticipating October 2026 for SB 343 to come into effect
- SB 343 will likely become national *de facto* standard due to supply chain complexities
- Businesses should review the draft material characterization study and plan for next steps

Another Restriction on Recyclability Claim is Use of Chasing Arrows Symbol

- Use of chasing arrows symbol constitutes a “recyclability” claim under SB 343
- **Prohibits** use of chasing arrows on rigid plastic bottle or container unless you meet ALL requirements for “recyclable” under SB 343 by the deadline
- **Prohibits** resin identification code (RIC) from being placed inside of a chasing arrows symbol, unless the rigid plastic bottle or plastic container meets requirements for statewide recyclability (ALERT RE: RIC 3, 6 and 7)
- Non-compliance risks lawsuits by Attorney General and/or private enforcer. The bar to sue will be low; significant uptick in litigation is anticipated
- Over 30 other states require RIC with chasing arrows, raising complex supply chain and compliance issues

Another Piece of the Puzzle: CA's Extended Producer Responsibility (EPR) Program

- CA's 2022 SB 54 "shifts the plastic pollution burden" from consumers and municipalities to producers, by enacting an extended producer responsibility (EPR) program
- The producer is typically the brand owner.
- Covered material categories list published December 31, 2024 at https://calrecycle.ca.gov/packaging/packaging-epr/cmclist/
- Register with CalRecycle on or before July 1, 2025.
- All producers participate in PRO (Circular Action Alliance) by January 1, 2027: report weight, material type and form of packaging; pay dues based on that report; fund and orchestrate PRO; reimburse state.
- Little power to small businesses.

Who Must Comply With SB54?

- Producers include brand owners, licensees, manufacturers, distributors, sellers of single use packaging in California
- Exemptions for small businesses
- Covered materials include plastic and other single use packaging (glass, paper, bamboo, metal)
- Who has the burden – manufacturers, retailers, wholesalers? All of the above

Source Reduction Goals in California

- By 2032, the PRO must implement a plan to achieve 25% source reduction by weight and 25% by plastic component for covered material
  - Source reduction = the reduction in the amount of covered material created by a producer
    - Methods include shifting covered material to reusable or refillable packaging, reusable product or eliminating unnecessary packaging
      - Source reduction does not include: (1) replacing a recyclable or compostable material with a nonrecyclable or noncompostable covered material, or a covered material that is less likely to be recycled or composted; or (2) switching from virgin covered material to postconsumer recycled content

California Plastic Recycling Goals

- Not less than 30 percent of covered material on and after January 1, 2028
  - Not less than 40 percent of covered material on and after January 1, 2030
    - Not less than 65 percent of covered material on and after January 1, 2032
      - $$$$$$$$$$$

Impact of CA EPR Requirements

- $10 / person x 50,000,0000 = $500,000,000 / year?
- + $500,000,000 / year for ten years (starting in 2027) must be deposited into Plastic Pollution Mitigation Fund (up to $150,000,000 / year from “plastic resin manufacturers”)
- CalRecycle estimates this cost spread across 13,615 producers
- Every packaging sustainability law stands on its own (PCR content, green washing, chemical bans, etc.) but EPR is the tie that can bind
- A single EPR law like CA’s SB 54 can incorporate all of those concepts into a single vehicle

Truth in Labeling Laws & SB 343

Questions to consider:

- Who is responsible for verifying “recyclable, biodegradable, compostable” on label? Manufacturer, brand, retailer?
- How to determine recyclability of product and if chasing arrows symbol can be used?
- Is testing acceptable for “biodegradable, compostable” claims? (i.e. OECD 301)
- Which teams are necessary to implement changes & ensure compliance with these laws? Recordkeeping?

Expect more challenges to environmental-related claims:

- Plaintiffs may allege that a representation is allegedly false under False advertising/Consumer Remedies Act/Unfair Competition
    - “Sustainable”
    - “Eco-friendly”
    - “Recyclable, compostable or reusable”

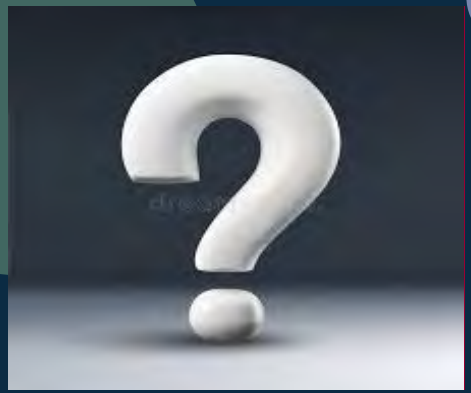
Compliance and Risk Mitigation Considerations

- Make a plan – the sea change these laws are forcing are challenging, but do not ignore them
- Be prepared – review your packaging portfolio, compare to and match final material characterization study when published.
- Be vigilant – these laws are fast approaching and requirements are perpetually evolving
- Be specific – keep an eye out for improved clarity as rulemakings continue
- Be consistent – across external communications, marketing, and recordkeeping
- Communicate – internally with stakeholders, and marketing and legal teams
- Participate! – get involved and leverage your relationships with trade associations, policymakers, etc.
- Get help – work with experts if your company needs help understanding this evolving landscape – we are available for detailed dive

Steptoe

www.steptoe.com

Questions ?
Please reach out.



Jennifer K. Singh,
San Francisco, CA
415.365.6722
jsingh@steptoe.com

Steptoe

www.steptoe.com

www.linkedin.com/company/steptoe-&-johnson-llp

@SteptoeLLP

For more information about Steptoe, the partners and their qualifications,
see **www.steptoe.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 Steptoe or models not connected with the firm.

Thank you for attending!

- Please complete the survey at the end of the webinar. We appreciate your feedback!
- AHPA Annual Member Meeting & Celebration of Life for Michael McGuffin
  - March 4, 2025: 8am -12pm at Sheraton Park Hotel - Anaheim
- AHPA Herb Walk at Fullerton Arboretum
  - March 4, 2025: 1-5pm (Departs from Anaheim Convention Center)
- AHPA Member Reception
  - March 5, 2025: 5:30-7:30pm at Sheraton Park Hotel - Anaheim
- Committee Meetings: Expo West & Spring
  - March 4 – March 13, 2025 (Hybrid)
- AHPA Workshop: Microscopic Identification & Macroscopic Assessment of Herbal Ingredients for cGMP Compliance
  - May 6-8, 2025: Weber State University in Ogden, UT
- AHPA Botanical Congress
  - September 16-17, 2025: Cincinnati, Ohio
  - In conjunction with United Plant Savers' International Herb Symposium