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LEGISLATION, REGULATIONS & STANDARDS

FDA Proposes Changes to Standards of Identity for Foods Including Salt

The U.S. Food and Drug Administration (FDA) has issued a proposed rule that would change the standards of identity (SOIs) for foods that include salt to allow for the use of safe and suitable salt substitutes.

The proposed rule, titled "Use of Salt Substitutes to Reduce the Sodium Content in Standardized Foods," seeks to support a healthier food supply by providing flexibility to facilitate industry innovation in the production of standardized foods to reduce sodium content, FDA said in a press release. The agency said the rule has the potential to help consumers gradually reduce their sodium intake.

"Today's action is another step forward in our efforts to improve nutrition and reduce chronic disease by providing manufacturers another tool to lower the use of sodium in food production. This approach may help reduce Americans' sodium intake and lower their risk of hypertension, a leading cause of heart disease and stroke," FDA Commissioner Robert Califf said in a statement.

Most SOIs do not currently allow the use of salt substitutes. The proposed rule does not provide a list of allowable salt substitutes, but rather defines them as safe and suitable ingredients to replace some or all of the salt in a standardized food. The proposed rule would have an effect on a wide variety of foods.

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FDA Issues Draft Guidance for Dietary Guidance Statements

The U.S. Food and Drug Administration (FDA) has issued draft guidance that provides food manufacturers with recommendations on how and when to use Dietary Guidance on food labels.

Dietary Guidance Statements are statements in food labeling that are based on key recommendations from consensus reports that discuss how a food or food group can be part of a nutritious dietary pattern, such as "Make half your grains whole grain," and "Eat leafy green vegetables as part of a nutritious dietary plan."

The guidance supports the agency's goal to help reduce the burden of chronic disease and advance health equity through improved nutrition. “Diet-related chronic diseases, are the leading causes of death and disability in the U.S. and disproportionally impact communities of color and people living in rural areas,” FDA Commissioner Robert Califf said in a statement. “The FDA is committed to being a part of the solution to improve the health of millions of Americans. Today’s action is another step towards helping consumers make informed choices about the foods they eat.”

The draft guidance can help improve consistency in food labeling and consumer understanding, as well as facilitate industry innovation toward healthier foods, FDA said.

European Commission: Nearly Half of Imported Honey Samples Suspicious for Adulteration

A European Union coordinated action seeking to assess the prevalence of adulterated honey on the market found that 46% of collected samples of imported honey are suspected of being adulterated with syrups, the European Commission (EC) has reported.

In its findings of the 2021 coordinated action, “From the Hives,” the EC said the rate of suspicious samples was substantially larger than the amount obtained in 2015-2017, which was 14%. The highest absolute number of suspicious samples originated from China, while honey originating from Turkey had the highest relative proportion of suspicious samples. Honey imported from the United Kingdom had a 100% suspicion rate, which the EC said was likely due to honey produced in other countries being blended in the UK before re-export to the EU.

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ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

The EC said it will discuss an appropriate follow-up, including inviting member states to increase controls on the market and at the EU's borders and to adapt their investigation techniques to better detect and fight food fraud.

"Analytical methods to ascertain honey authenticity exist but are lagging behind and lack sufficient sensitivity to detect low and intermediate levels of sugar adulterations," the report said. "Fraudsters are adapting the level of adulteration with extraneous sugars in honey to this analytical capability. The same analytical limitations apply to border controls."

Perdue Foods Petitions USDA to Remove 'Pasture-Raised' as Synonymous with 'Free Range'

Perdue Foods has filed a petition calling on the U.S. Department of Agriculture (USDA) to promulgate labeling regulations that remove "pasture-raised" from claims considered synonymous with "free range" and amend its current Compliance Guideline to separately define the two phrases.

The company is asking USDA's Food Safety and Inspection Service (FSIS) to amend its interpretation of "free range"-raised chicken to mean chickens that spend the majority of their lives physically on "pasture," with "pasture" defined as "a majority of rooted-in-soil vegetative cover."

Perdue said USDA currently defines "free range" as "access to the outside," and considers the following claims synonymous: "free roaming," "pasture fed," "pasture grown," "pasture raised" and "meadow raised." Perdue argued that USDA's current definition of free range cannot be considered synonymous to the other terms because each phrase is understood to mean different things by consumers.

"The key difference is that 'free range' does not require that the animal actually spend any time on the ground or on the pasture itself—only that the chickens have access to the outdoors," the company said in the petition. "Conversely, 'pasture-raised,' according to the Consumer Survey referenced herein, well more than half of respondents indicated that they believe 'pasture raised' chickens are guaranteed to spend the majority of their lives raised on pasture."

EFSA Raises Concerns About Nitrosamines in Food

The European Food Safety Authority (EFSA) has released an assessment concluding that exposure to nitrosamines is a health concern for people of all ages across the European Union.

The European Commission asked EFSA to assess the public health risk related to nitrosamines, which are the reaction products of nitrosating agents such as nitrates or nitrogen oxides and amino-based substances and may be formed in a variety of foods under processing conditions in the presence of these reactants. They have been detected in cured meat products, processed fish, beer and other alcohol and non-alcohol beverages, cheese, soy sauce, oils, processed vegetables and human milk. Ten nitrosamines found in food are carcinogenic and genotoxic, EFSA said in a news release.

"Our assessment concludes that for all age groups across the EU population, the level of exposure to nitrosamines in food raises a health concern," Dieter Schrenk, chair of the Panel on Contaminants in the Food Chain, said in a statement. "Based on animal studies, we considered the incidence of liver [tumors] in rodents as the most critical health effect."

EFSA said knowledge gaps currently exist about the presence of nitrosamines in specific food categories, and balancing a diet with a wider variety of foods could help consumers reduce their intake of nitrosamines. EFSA will share its opinion with the European Commission, which will then consider what risk management measures are needed.

FDA Outlines Strategy for Infant Formula Market

The U.S. Food and Drug Administration has released a national strategy outlining actions it will take immediately to help increase the resiliency of the U.S. infant formula market and supply. The Food and Drug Omnibus Reform Act of 2022 (FDORA) directed the agency to develop the strategy. Key elements of the strategy, released March 28, include the following:

- Ensuring the industry is aware of requirements to develop and implement redundancy risk management plans;
- Continuing to enhance inspections of infant formula manufacturers;
- Expediting review of premarket submissions for new infant formula products;
- Continuing to monitor the infant formula supply and developing a forecasting model to enable FDA to prepare for and mitigate future supply disruptions;
- Continuing to advance the agency's strategy to help prevent Cronobacter illnesses;
- Improving the agency's consumer education materials; and

- Enhancing and leveraging FDA's partnerships with health care providers and professionals.

"Safety and supply go hand-in-hand. We witnessed last year how a safety concern at one facility could be the catalyst for a nationwide shortage. That's why we are looking to both strengthen and diversify the market, while also ensuring that manufacturers are producing infant formula under the safest conditions possible," FDA Commissioner Robert Califf said in a statement. "Now, with this strategy, we are looking at how to advance long-term stability in this market and mitigate future shortages, while ensuring formula is safe."

FDA Issues Guidance for Beer Labeling

The U.S. Food and Drug Administration has issued a guidance document intended "to assist manufacturers on how to label bottled or otherwise packaged beers that are subject to the Food and Drug Administration's (FDA's) labeling laws and regulations" following a ruling by the Alcohol and Tobacco Tax and Trade Bureau clarifying that certain beers "do not meet the definition of a 'malt beverage.'"

The guidance applies to beers that are "not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice, or wheat) or are made without hops." These products do not meet the definition of a "malt beverage" and are not subjected to malt beverage provisions of the Federal Alcohol Administration Act; however, their labels must comply with Food and Drug Administration requirements, such as the inclusion of a statement of identity, the net quantity of product, the name and location of the manufacturer and a statement of ingredients.

Codex Alimentarius Meeting on Pesticide Residues Set for May

The U.S. Department of Agriculture has announced a public meeting to be held on May 25, 2023, to discuss the agenda items and draft U.S. positions for the Codex Alimentarius Commission's meeting on pesticide residues in late June. Issues to be discussed include revisions to *Classification of Food and Feed*.

LITIGATION

California Ban on SSB Taxes Is Unconstitutional, Appeals Court Affirms

A California appellate court has affirmed a ruling holding that a statewide ban on municipalities implementing taxes on sugar-sweetened beverages (SSBs) and other foods is unconstitutional. *Cultiva La Salud v. California*, No. 34-2020-80003458 (Cal. App. Ct., 3d Dist., entered March 27, 2023). A health advocacy organization and a city council member had challenged the Keep Groceries Affordable Act of 2018, arguing that the statewide prevention on SSB taxes that the law imposed violated the "home rule" doctrine in the state constitution, which "allows charter cities to 'make and enforce all ordinances and regulations in respect to municipal affairs.'"

The court focused on the law's provision penalizing charter cities that imposed a tax on groceries. "The Legislature wanted to discourage charter cities from enacting a tax, fee, or assessment on groceries, even if it could not lawfully prohibit them from doing so," the court held. "[T]he Legislature's sole purpose in imposing the penalty was 'to chill the assertion of constitutional rights.' [] That is not … a legitimate regulatory objective. It is instead a 'patently unconstitutional' objective."

Court Denies Bid to Dismiss Texas Toast "No Preservatives" Claims

A federal court in New York has denied an attempt by T. Marzetti Co. to dismiss claims that its Texas toast products labeled and advertised as containing "No Preservatives" misled consumers. *Simeone v. T. Marzetti Co.*, No. 21-9111 (S.D.N.Y., entered March 23, 2023).

The products at issue in the proposed class action—including the company's Ultimate Garlic, Real garlic, Five Cheese and Real Parmesan Texas Toast products—are frozen bread slices covered with a flavored spread. The plaintiffs alleged that the products are packaged in boxes labeled and advertised as containing "No Preservatives," which they said was misleading because the flavoring spread contains citric acid. They assert that the U.S. Food and Drug Administration's (FDA) regulations classify citric acid as a preservative.

The defendant sought to dismiss the suit, arguing the plaintiffs failed to plausibly allege that the "No Preservatives" labeling is misleading. The court disagreed, finding the plaintiffs' allegations sufficient to establish that citric acid functions as a preservative in the products and to state a claim for material misrepresentation.

The company also argued that the plaintiffs' claims are preempted by federal law because they seek to impose a requirement that citric acid always be noted as a preservative when in a product, a more stringent standard than FDA imposes.

"Defendant's argument fails because it is based on a faulty construction of Plaintiffs' claims," the court said in its opinion. "Plaintiffs do not argue that Defendant must include additional labelling, rather, Plaintiffs claim that Defendant's existing labelling is misleading, and that Defendant is liable for that misrepresentation. Thus, Plaintiffs' claims are not preempted by the [Food, Drug and Cosmetic Act] because they do not address the sufficiency of Defendant's labelling under the FDCA but rather its truthfulness."

Court Dismisses Part of Gerber Nutrient Claim Case

A federal court in California has pared down a lawsuit alleging Gerber made unlawful nutrient claims on several of its products for infants and children under the age of two. *Howard v. Gerber Products Co.*, No. 22-4779 (N.D. Cal., entered March 29, 2023). The plaintiff in the proposed class action alleged that Gerber violated federal regulations by including nutrient content claims on its products intended for use by infants and young children, and also that the labels on the products are false and misleading.

Gerber sought dismissal, arguing that its statements are not unlawful under U.S. Food and Drug Administration (FDA) regulations. The court determined that some of the statements on Gerber's products, including "Grow Strong," "Wonderfoods awaken toddler's love for nutritious foods" and "Gerber Natural for Toddlers brings the goodness of naturally nutritious fruits selected and made with strict quality standards just for toddlers," are implied nutrient content claims and can move forward. The statements "made with real veggies," "made with real veggies & fruits" and "made with super foods whole grains" are not nutrient content claims, the court ruled.

Gerber also argued that statements about the percentage of vitamins and minerals in its products are allowed by FDA regulations. The court said that the regulations require statements to be explicitly quantitative and involve a specific percentage.

"Gerber's statements do more than state the percentage of a vitamin—for instance, one product says, 'Supports toddler's healthy growth with 15% DV of calcium and 2g protein,'" the court said. "That goes far beyond what the FDA has authorized by regulation, and so the claims based on these statements can move

forward." The court granted dismissal with leave to amend, allowing the plaintiff to amend the complaint if discovery on her surviving claims reveals information relevant to the dismissed claims.

'Alcohol Alternative' Contains Addictive Ingredient, Consumer Alleges

A plaintiff has filed a putative class action alleging that Feel Free Wellness Tonic, marketed as a kava-based "safe, sober, and healthy alternative to alcohol," has "the potential to be highly addictive" because its "primary ingredient is not kava, but kratom," an "opioid that carries similar risks of addiction as controlled narcotics." *Torres v. Botanic Tonics LLC*, No. 23-1460 (N.D. Cal., filed March 28, 2023).

The consumer further argues that Botanic Tonics "manipulated the formula of Feel Free to magnify the effects of kratom and induce a quicker, longer-lasting, and greater high." He alleges that he, while recovering from an alcohol addiction, tried the beverage in December 2021 and developed a "strong addiction to the product" within three months, spending $3,000 per month on the beverage to consume 10 Feel Free tonics each day. "Botanic Tonics has marketed its product misleadingly to this vulnerable population and failed to warn about the dangerous side effects of the product," the complaint asserts.

For allegations of false advertising, fraud, breach of warranty and unjust enrichment, the plaintiff seeks class certification, damages, restitution, costs and attorney's fees.

Court Denies Bid to Dismiss Protein Claims Against Nature's Path Foods

A federal court in California has denied an effort to throw out a proposed class action alleging that Nature Path Foods deceived consumers about the amount of protein in its breakfast and snack products. *Brown v. Nature's Path Foods, Inc.*, No. 21-05132 (N.D. Cal., entered March 29, 2023). The plaintiffs are three California consumers who allege they were deceived into buying Nature's Path's breakfast and snack products based on statements the company made on product packaging about the amount of protein in its products.

Nature's Path sought to dismiss the plaintiffs' second amended complaint, arguing in part that the plaintiffs lacked standing to

pursue claims based on the company's alleged omission of a percent daily value on the products' Nutrition Facts Panel. The court found, however, that the plaintiffs plausibly alleged that they were deceived by the omission, allowing the claim to proceed.

"Further, while establishing the ultimate persuasiveness of this claim on the merits may be an uphill battle under the circumstances, the Court cannot conclude at this stage that the fact that Plaintiffs looked at the two-column side label makes their reliance allegations inherently implausible as a matter of law," the court said in the order.

The court also allowed the plaintiffs' claim regarding the prominence of labeling indicating the product had 10 grams of protein per serving with milk to proceed, and determined that the plaintiffs have standing to seek injunctive relief.

Sweetgreen Agrees to Rename Bowl Following Chipotle Suit

Two days after Chipotle Mexican Grill filed a lawsuit against Sweetgreen alleging its "Chipotle Chicken Burrito Bowl" infringed on its trademark, the two companies have reportedly come to an agreement to drop the lawsuit and rename the bowl. *Chipotle Mexican Grill Inc. v. Sweetgreen Inc.*, No. 23-00596 (C.D. Cal., filed April 4, 2023). The bowl will now be named the "Chicken + Chipotle Pepper Bowl" as part of a tentative agreement. A Sweetgreen spokesperson said the change was made "to focus on business and continue serving our guests without distraction."

"Our mission is to bring customers healthy, elevated and craveable menu items that make you feel good," the spokesperson said in a statement. "We are looking forward to putting this lawsuit behind us as we continue to connect more people to real food."

Chipotle's suit followed the March 30 unveiling of Sweetgreen's bowl, which Chipotle alleged contains similar ingredients to its own burrito bowls. Chipotle also asserted in its complaint that Sweetgreen uses "CHIPOTLE" in a font nearly identical to Chipotle's stylized mark, and its social media presence allegedly confirmed its intent to create a false association with Chipotle and trade off of Chipotle's marks.

The choice of a lawyer is an important decision and should not be based solely upon advertisements.