



LEGISLATION, REGULATIONS & STANDARDS

## FDA Commissioner Announces Redesign of Human Foods Program

U.S. Food and Drug Administration (FDA) Commissioner Robert M. Califf announced in a Jan. 31 statement that the agency intends to reorganize its Human Foods Program and Office of Regulatory Affairs (ORA) after receiving the results of an external evaluation of the program conducted by an expert panel of the Reagan-Udall Foundation.

FDA commissioned the review, which identified several issues with the agency's culture. In a statement, Califf said the agency has carefully reviewed the findings of the panel, as well as the findings of a separate review of the agency's infant formula supply chain response.

"The findings and recommendations from these reviews identified issues surrounding culture, structure, resources, and authorities," he said. "They also noted several areas of need, including modernizing data systems, providing more resources and authorities, improving emergency response systems, and building a more robust regulatory program."

The restructuring plan calls for functions of the Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Policy and Response (OFPR) and certain functions of ORA to be unified into a new organization, the Human Foods Program. Califf said FDA will hire a deputy commissioner to oversee the program.

Califf said ORA's operating structure will be transformed into an "enterprise-wide organization supporting the Human Foods

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Program and all other FDA regulatory programs by focusing on its critical activities.”

“This realignment will allow ORA to be singularly focused on excellence in its core mission—inspections, laboratory testing, import, and investigative operations,” he said. “This will optimize ORA’s operations in line with the FDA’s public health and prevention-oriented goals.”

Califf said FDA has formed a group to develop a detailed plan. He anticipates additional public updates on the reorganization by the end of February 2023.

## USDA to Update School Lunch Nutrition Standards

The U.S. Department of Agriculture (USDA) is proposing updates to nutrition standards for school meals, including limiting added sugars and reducing sodium. On February 3, Agriculture Secretary Tom Vilsack announced the proposed changes as part of multiple initiatives to support and enhance the health of America’s children through nutritious school meals.

“Our commitment to the school meal programs comes from a common goal we all share – keeping kids healthy and helping them reach their full potential,” Vilsack said. “Many children aren’t getting the nutrition they need, and diet-related diseases are on the rise. Research shows school meals are the healthiest meals in a day for most kids, proving that they are an important tool for giving kids access to the nutrition they need for a bright future. We must all step up to support child health if we are to achieve the Biden-Harris Administration’s goal of ending hunger and reducing diet-related diseases by 2030, in accordance with the National Strategy on Hunger, Nutrition and Health. Strengthening school meals is one of the best ways we can achieve that goal.”

The department’s Food and Nutrition Service (FNS) is proposing new science-based standards developed from the latest edition of the dietary guidelines. FNS is proposing a gradual, multi-year approach to implementing updates to the nutrition standard, including:

- Limiting added sugars in certain high-sugar products, and later, across the weekly menu;
- Allowing flavored milk in certain circumstances and with reasonable limits on added sugars;
- Incrementally reducing weekly sodium limits over many school years; and



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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.



- Emphasizing products that are primarily whole grain, with the option for occasional non-whole grain products.

FNS is seeking public comment on the proposed standards rule. The 60-day comment period began February 7, 2023.



## FDA Announces Update on Lead Levels in Baby Foods

The U.S. Food and Drug Administration (FDA) has issued draft guidance for industry on action levels in baby foods. The action levels listed in the guidance are 10 parts per billion for fruits, vegetables, mixtures, yogurts, custards/puddings and single-ingredient meals; 20 parts per billion for root vegetables; and 20 parts per billion for dry cereals.

“Although it is not possible to remove these elements entirely from the food supply, we expect that the recommended action levels will cause manufacturers to implement agricultural and processing measures to lower lead levels in their food products below the proposed action levels, thus reducing the potential harmful effects associated with dietary lead exposures,” a press announcement stated. “Although not binding, the FDA would consider these action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case.”

The agency’s announcement was issued days after a putative consolidated class action against Beech-Nut Nutrition Co. was dismissed for lack of jurisdiction, finding FDA had primary jurisdiction on the issue of heavy metals in baby food. *In re Beech-Nut Nutrition Co. Baby Food Litig.*, No. 21-0133 (S.D.N.Y., entered January 20, 2022).

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### LITIGATION

## Court Approves \$4M Judgment in Ice Cream-Linked *Listeria* Wrongful Death Suit

A federal court in Florida has approved \$4 million in damages in a default judgment against Big Olaf Creamery in a wrongful death suit brought against the company by the estate of a woman who died of a *Listeria monocytogenes* infection from eating the company’s ice cream. *Billman v. Big Olaf Creamery, LLC*, No. 22-1514 (M.D. Fla., entered January 24, 2023).

The woman visited Big Olaf's Sarasota, Florida, ice cream parlor and ate the contaminated ice cream, according to the amended complaint. The following week, she developed gastrointestinal symptoms and a low-grade fever. Her symptoms persisted and she was hospitalized after having a 103-degree fever. She died of septic illness three days after entering the emergency room. The default judgment included \$3 million in compensatory damages and \$1 million in punitive damages.

According to the complaint, she was one of a total of 28 people in 11 states whom the U.S. Centers for Disease Control and Prevention (CDC) reported infected with an outbreak of *Listeria* traced to Big Olaf Creamery. She was the only person who died from the outbreak. In July 2022, CDC advised consumers who had Big Olaf Creamery ice cream at home to throw away any remaining product.

## Court Dismisses Claims that Cheesecake Factory 'Brown Bread' Misleads Consumers

A federal court in Illinois has dismissed a consumer's proposed class action alleging the manufacturer of The Cheesecake Factory-branded "Brown Bread" misleads consumers about the bread containing whole grains rather than refined grains. *Hamidani v. Bimbo Bakehouse LLC*, No. 22-1026 (N.D. Ill., entered January 12, 2023).

The plaintiff alleged that Bimbo Bakehouse LLC deceived consumers by misrepresenting the whole grain content of its wheat sandwich bread sold under The Cheesecake Factory brand. The product was sold with the labeling "Our Famous 'Brown Bread,'" and primarily contains enriched wheat flour made from refined grains, the court wrote in its opinion. The product is made with molasses and caramel color, which gives the bread its darker color, and contains oat and rye flakes on top of the bread. The plaintiff alleged the bread's physical appearance and labeling deceived her into thinking the bread had more whole grains than refined grains.

Bimbo Bakehouse moved to dismiss the suit for lack of standing and failure to state a claim. The court agreed, finding that the bread's appearance and label makes no explicit or implicit representation about the proportion of whole grains in the bread's ingredients.

The court said even if the brown color of the bread signified that the bread contained whole grains, it does not guarantee its precise whole grain content. Additionally, the court said the defendant's

use of the phrases “Brown Bread” and “wheat sandwich loaf” make no reference to “whole wheat” or “whole grains.”

“The presence of oat and rye flakes on the exterior of the Bread does not move the needle,” the court said. “No reasonable consumer could conclude what percentage of whole wheat the Bread contains merely by these toppings. Plaintiff has not identified any plausible deception in the Product’s packaging or physical appearance.”

The court determined the plaintiff’s interpretation of the product’s representations is unreasonable and dismissed her consumer fraud claims. The court also dismissed the remainder of the plaintiff’s claims.

## Kellogg Faces Class Action Over Smart Start Cereal Protein Claims

A New York consumer has filed a proposed class action against Kellogg Sales Co. alleging it misleads consumers about the protein content of its Smart Start cereal. *Jones v. Kellogg Sales Co.*, No. 23-00049 (W.D.N.Y., filed January 19, 2023).

The plaintiff highlights in the complaint that the cereal’s prominent claim of “11g of Protein” on its packaging appeals to a growing number of consumers seeking foods with significant amounts of protein. The cereal’s packaging notes that six grams of protein come from milk, while five grams come from the cereal itself. The plaintiff alleges that the front label indicating that the protein contribution of the cereal and milk are roughly equivalent is misleading.

“The six grams of protein from added milk supplies 12% of the daily value for protein in contrast to the 4% from the cereal alone,” she said in the complaint. “In contrast to the front label indicating the protein contribution from the cereal and milk is roughly equivalent, the former provides only 25% of the Product’s protein content while 75% is provided by milk.”

For alleged violations of New York and other state consumer fraud laws, as well as alleged breach of express and implied warranties, fraud and unjust enrichment, the plaintiff is seeking class certification, damages and costs and expenses including attorney’s fees.

## Court Narrows Claims in Kraft Mac & Cheese Phthalates Suit

A federal court has narrowed a proposed consumer class action alleging the Kraft Heinz Co. deceives consumers by omitting information about phthalates in its popular macaroni and cheese product. *Stuve v. The Kraft Heinz Co.*, No. 21-1845 (N.D. Ill., entered January 12, 2023).

The plaintiffs allege that packaging touting the product's positive attributes, including that it is free of artificial preservatives, flavors and dyes, misleads consumers into believing the product is healthy, wholesome, nutritious and free from artificial substances, when the product contains phthalates, a type of synthetic chemical that can have adverse health effects. Their suit alleged violations of multiple state consumer fraud and deceptive business practice laws, unjust enrichment, breach of implied warranty and breach of express warranty.

Kraft sought to dismiss the claims, and received a ruling partially in its favor. In the opinion, the court noted that the plaintiffs do not allege the product contains artificial preservatives, flavors or dyes, just that the statements lead consumers to believe products are wholesome, safe and healthy, and do not contain dangerous chemicals or artificial substances such as phthalates.

"Plaintiffs have not stated a plausible claim in this regard," the court said in the opinion. "The alleged presence of a negative substance does not prohibit a manufacturer from advertising a product's positive qualities."

The court denied Kraft's motion to dismiss claims regarding material omissions, unjust enrichment and a claim brought by a Massachusetts plaintiff of breach of implied warranty.

## MiO Malic Acid Claims Dismissed

A New York federal court has dismissed with prejudice a lawsuit alleging Kraft Heinz Foods Co. misled consumers by touting MiO liquid water enhancers as containing natural flavoring despite listing malic acid as an ingredient. *Hoffman v. Kraft Heinz Foods Co.*, No. 22-0397 (S.D.N.Y., entered February 7, 2023). The plaintiff had alleged that MiO contains DL-Malic acid, the artificial form of malic acid, thus purportedly contradicting the company's representation of the flavoring as natural.

The court found that the plaintiff "plainly offers conclusory allegations about the *possibility* that the Product contains artificial DL-Malic acid, without any additional factual support from product testing. ... And in an effort to substantiate the claim, Plaintiff again asserts—without any support—that amorphous 'laboratory analysis' concluded that the Product contained

artificial malic acid instead of its natural form. [ ] Even taking the allegations as true—as this Court must in this context—the allegations in the Amended Complaint are a far cry from raising 'any factually substantiated allegations' that the Product contains artificial malic acid, rather than natural malic acid."

In addition, the court was unpersuaded by the plaintiff's allegation that the label violated U.S. Food and Drug Administration (FDA) regulations on flavoring, noting that "it is well established in this Circuit that the Amended Complaint 'could not allege a claim for private enforcement of FDA regulations.'"

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