



LEGISLATION, REGULATIONS & STANDARDS

Evaluation of FDA Human Foods Program Finds Culture of “Constant Turmoil”

An [independent review](#) commissioned by the U.S. Food and Drug Administration (FDA) of the Human Foods Program has reportedly identified several issues with the agency’s culture. The key findings of the Reagan-Udall Foundation for the FDA’s report were:

- “FDA has dedicated staff who are committed to protecting public health, but the current culture of the FDA Human Foods Program is inhibiting its ability to effectively accomplish this goal.”
- “While the Human Foods Program has specified functions, a clear unifying vision and mission for the entire program is not apparent.”
- “The lack of a single clearly identified person to lead the Human Foods Program has adversely impacted the organizational culture and led to overlapping roles and competing priorities that result in what is perceived as constant turmoil.”
- “The Human Foods Program approach of relying on consensus has significant drawbacks for making decisions about taking regulatory action.”
- “A culture of cooperation and accountability in the Human Foods Program’s field operations needs to be reestablished to fulfill the potential of program alignment and to optimize the performance of the Human Foods Program.”

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PDF ARCHIVES

Note: The Food and Beverage Litigation and Regulatory Update website is under construction this week.

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- “The Human Foods Program culture appears to foster an aversion to risk that undercuts its ability to meet its public health mandate.”

The report makes a number of recommendations for improvement, including (i) nurturing “a culture where regulatory decision-making is rooted in scientific evidence”; (ii) establishing “an organizational structure with a clear leader”; and (iii) committing to “transparency, timeliness, and predictability in decision-making, with a preference towards action.”

FDA Commissioner Robert Califf responded in a [statement](#), noting that he will form a “group of agency leaders to advise me on how best to implement and operationalize these findings.”

“The Human Foods Program is a top priority for the agency,” Califf said in the statement. “America’s food supply is as safe as it’s ever been, and our Foods Program experts have significantly contributed to the availability of more safe and nutritious food options for consumers. That said, over the past several years, the program has been stressed by the increasing diversity and complexity of the nation’s food systems and supply chain, the ongoing impacts associated with climate change and rapid advances in the science underlying many of the foods we eat today.

“Each of these factors point to the need to evolve our existing Foods Program leadership and structure and identify new ways to fund these mission critical activities. In addition, the agency’s inspectional activities, including those conducted in collaboration with our state and international partners, are critical in order to assure a safe and high-quality food supply. And finally, the need to maintain upgraded digital technology systems that allow us to stay ahead of the vast and growing food system, are essential components of any future plan.”

FTC Seeks Input on Environmental Marketing Claims Guidelines

The Federal Trade Commission (FTC) is [seeking public feedback](#) on potential updates and changes to the Green Guides for the Use of Environmental Claims. Food and beverage manufacturers rely on the guidelines to avoid making environmental marketing claims that are unfair or deceptive under Section 5 of the FTC Act. According to an FTC news release, increasing consumer interest in buying environmentally friendly products has prompted the need for updates to the guidelines.



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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

“Consumers are increasingly conscious of how the products they buy affect the environment, and depend on marketers’ environmental claims to be truthful,” Bureau of Consumer Protection Director Samuel Levine said. “We look forward to this review process, and will make any updates necessary to ensure the Green Guides provide current, accurate information about consumer perception of environmental benefit claims. This will both help marketers make truthful claims and consumers find the products they seek.”

The Green Guides were first issued in 1992, and most recently updated in 2012. They provide guidance on environmental marketing claims, including how consumers are likely to interpret particular claims and how marketers can substantiate their claims to avoid deceiving consumers.

The FTC is specifically seeking comments on the following issues:

- Carbon offsets and climate change;
- The term "recyclable";
- The term "recyclable content"; and
- The need for additional guidance.

The notice announcing the opening of the public comment period will be published in the Federal Register in mid-January 2023, after which the agency will accept comments for 60 days.

Scientists Call for Greater Regulation of Energy Drinks in EU, While U.S. Company Accused of Advertising to Minors

Increased consumption of energy drinks is prompting scientists in Europe to call for a regulatory framework addressing products' maximum levels of active ingredients, volume size and labeling in an [article](#) in the journal *Nutrients*. The scientists note recent studies showing that during the COVID-19 pandemic, people are consuming more energy drinks (EDs) both in terms of frequency and volume.

"There is a global growing concern about the potential risks and the existing low-risk perception associated with these drinks," they said. "In general, the evidence correlates EDs with a significant increase in the odds of insomnia (and

inspections, subject to FDA, USDA and FTC regulation.



jitteriness/activeness), anxiety, depression, impulsivity and poor academic performance, among others."

The authors note that management of the risks derived from exposure to three of energy drinks' active ingredients—caffeine, D-glucuronolactone and taurine—would be strengthened by the creation of a legal framework at a European level in terms of setting maximum limits for the active components and their possible combinations.

The authors also suggest increasing collaboration between risk managers and regulators with the industry and community to optimize labeling, portion sizes and risk communication.

Interest in mitigating the effects of energy drinks is not limited to Europe. The U.S.-based organization [Truth in Advertising](#) has sent a warning letter to Ghost, LLC and filed complaints with the Federal Trade Commission and the U.S. Food and Drug Administration after purportedly finding the company allegedly markets energy drinks and supplements to children despite the fact that the products are not intended for minors and may be harmful to minors.

The group also alleges Ghost fails to properly disclose that their products are only intended for healthy adults, makes unsubstantiated and unapproved health claims about its products and uses deceptive social media influencer marketing.

ASA Bans Ad Touting Fruit-Flavored Beers As 'One of Your Five a Day'

The U.K.'s Advertising Standards Authority (ASA) has barred Scottish brewery BrewDog from using email marketing insinuating that its fruit-flavored beers contribute to consumers' consumption of five fruits or vegetables a day.

ASA received and investigated a complaint about a July 20, 2022, marketing email with a subject line "One of your five a day." The email included text about the brewery's fruit-flavored beers, including its "Lost in Guava," "Pineapple Punch" and "Lost in Lychee and Lime" beers. The complaint alleged that the claim "One of your five a day"—a reference to the U.K. government's advice to eat five daily portions of fruit and vegetables—was misleading.

According to ASA, BrewDog acknowledged that the beers advertised did not contribute to a consumer's "five a day." They also said they believed the email recipients were likely familiar with craft beer industry marketing highlighting fruity flavors and

fruit-inspired product names, as well as with BrewDog's playful marketing style.

ASA upheld the complaint, stating that while many consumers would be aware that some craft beers contained an unusually high amount of fruit, in general, consumers would be uncertain as to whether an alcoholic beverage with fruit content counted toward one's daily recommended fruit and vegetable intake.

"We therefore considered consumers were likely to interpret the claim 'One of your five a day' to mean that the fruit flavoured beers in the ad's body copy counted towards the recommended five daily portions of fruits and vegetables," ASA said. "Because alcoholic drinks did not count towards a person's '5 a day,' we concluded the claim was misleading." ASA ordered that the ad must not appear again in the same form.

LITIGATION

Judge Tosses Claims That Trader Joe's Cold-Pressed Juice Misled Consumers

A federal judge in Illinois has thrown out a putative class action alleging that Trader Joe's misled consumers about the freshness of its cold-pressed juice, ruling that the product's claims are not misleading and the plaintiff interpreted the labeling unreasonably. *Cristia v. Trader Joe's Co.*, No. 22-1788 (N.D. Ill., entered December 9, 2022).

The plaintiff asserted that labeling the juice as "cold pressed" is misleading because the juice is manufactured using high-pressure processing. Her suit included claims brought under the Illinois Consumer Fraud and Deceptive Practices Act, the Magnuson-Moss Warranty Act and other state consumer-protection statutes.

Trader Joe's disputed the claims and filed a motion to dismiss. The grocer also asked the court to take judicial notice of a public service announcement issued by the U.S. Food and Drug Administration (FDA) stating that most of the juice sold in the United States is pasteurized to kill harmful bacteria and juice products may also be treated by non-heat processes for the same purpose.

The court agreed to take judicial notice and granted the motion to dismiss. The court ruled that the plaintiff's interpretation of the cold-pressed juice label is unreasonable and that the label is not deceptive as a matter of law.

The court noted that the plaintiff acknowledges in her complaint that the juice is in fact cold-pressed, "meaning she is challenging a factually accurate statement."

"Moreover, plaintiff provides only conclusory factual allegations to suggest that unspecified 'consumers' agree with her subjective interpretation of the label," the court said.

Putative Class Action Alleges “Ranch Water’ Should Contain Tequila

A consumer has alleged that Heineken USA Inc. misleads consumers by selling Dos Equis XX Ranch Water hard seltzer in Classic Lime flavor because “ranch water” implies to consumers that the product will contain tequila and lime. *Pautz v. Heineken USA Inc.*, No. 22-2911 (S.D. Ill, E. St. Louis Div., filed December 12, 2022). The complaint describes the history and evolution of the “ranch water” cocktail, noting that the recipe typically contains tequila, water and lime. “Consumers will expect the Product contains ingredients associated with ranch water because that is what the packaging and label tells them,” the plaintiff alleges.

Further, the complaint asserts that the “hard” in “hard seltzer” implies to purchasers that the source of alcohol is hard liquor rather than the “Alcohol (from sugar)” indicated on the ingredient list. “Malt beverages such as the Product are required to indicate the class they fit into,” the plaintiff argues. “Ranch Water’ above ‘Hard Seltzer’ does not identify the Product’s base class and/or type designation, which is beer. . . . The representations are misleading because ‘Hard Seltzer’ does not indicate the class of malt beverages the Product fits in, preventing consumers from knowing the type of alcoholic drink they are buying.” For allegations of negligent misrepresentation, fraud and unjust enrichment along with alleged violations of Illinois’ consumer-protection statutes, the plaintiff seeks injunctive relief, damages, costs and expenses.

MEDIA COVERAGE

Consumer Reports Publishes on Lead and Cadmium in Dark Chocolate

Consumer Reports (CR) has published an [article](#) asserting that of 28 dark chocolate bars the organization’s scientists tested, all purportedly had detectable levels of cadmium and lead. The researchers reportedly used California’s maximum allowable dose level, noting, “We used those levels because there are no federal

limits for the amount of lead and cadmium most foods can contain, and CR's scientists believe that California's levels are the most protective available." The organization's previous research on contaminants in food has been cited in putative class action complaints, including a [complaint](#) on the levels of lead and arsenic in grape juice.

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