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**FIRM NEWS**

## Webinar: FDA Just Left... So Now What? Responding to a 483

Shook Of Counsel [John Johnson](#) joins AIB International's Judi Lazaro for another [installment of their webinar series](#) answering commonly asked questions about FDA regulations. Join Johnson and Lazaro on October 25, 2021, at 1:00 p.m. CT to learn more about how to respond to an FDA inspector's finding of objectionable conditions.

483 may be the most dreaded number in food safety. This number is the designation for a form where an FDA inspector records objectionable conditions in your facility that may be violations of the Food, Drug, and Cosmetic Act. If an inspector hands you a Form 483, the next question is, "Now what do I do?" For the third webinar in this series, join John Johnson from the law firm Shook, Hardy & Bacon and AIB International's Judi Lazaro, who have amassed decades of food safety and FDA compliance experience. They will ask each other those questions you've always wanted to ask and then answer with stories and practical tips. Come ready with your questions, as they'll end the session with an open Q&A.

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Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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## FDA Issues Guidance on Sodium Reduction for Food Producers

The U.S. Food and Drug Administration (FDA) has released [guidance](#) on limiting sodium in processed and packaged foods. “Limiting certain nutrients, such as sodium, in our diets plays a crucial role in preventing diseases like hypertension and cardiovascular disease that disproportionately impact racial and ethnic minority groups; these diseases often result in hundreds of thousands of lives lost and billions in annual health care costs,” the agency stated in a [press release](#). The statement notes that “people consume 50% more sodium than recommended,” and “about 70% of the sodium we eat comes from packaged, processed and restaurant foods.”

“[W]e recognize that most of the food consumption in the U.S. comes from a relatively small number of products and menu items in the marketplace that are produced by a limited number of food manufacturers,” the guidance states. “It is possible that reformulation by these food manufacturers could lead to increased demand for lower-sodium versions of ingredients used to produce packaged and prepared foods.” FDA notes that it specifically targets two categories of food producers with the guidance: (i) “[f]ood manufacturers whose products make up a significant proportion of national sales in one or more categories” and (ii) “[r]estaurant and similar retail food chains that are national or regional in scope.”

## FDA Releases Guidance on Food Contact Substance Notifications

The U.S. Food and Drug Administration (FDA) has released two guidance documents on food contact substance notifications, pertaining to [toxicology recommendations](#) and [administrative processes](#). The food contact substance notification process is “the primary means by which FDA regulates food additives that are food contact substances (FCSs).” The guidance documents define a food contact substance as “any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if the use is not intended to have any technical effect in the food,” per the federal Food, Drug, and Cosmetic Act.

## UK Launches Project to Minimize Food “Greenwashing”



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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

The U.K. Environment Agency has announced a project “to establish standardised metrics to measure environmental performance of the food and drink sector.” The agency “is aiming to make it simpler for businesses and for the public to understand the environmental performance of companies in key areas such as greenhouse gas reduction and resource efficiency,” according to the announcement. The agency indicated that it intends to incentivize companies to establish “greener manufacturing processes and business operations helping to tackle climate change” and positioned the project as an aid to businesses intending to “effectively communicate their environmental performance to the public.”

inspections, subject to FDA, USDA and FTC regulation.



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## LITIGATION

### Shortbread Cookies Lack Expected Butter, Consumer Alleges

A plaintiff has alleged that Mondelez Global LLC misleads consumers about the butter content of its Lorna Doone shortbread cookies. *Troutt v. Mondelez Global LLC*, No. 21-1279 (S.D. Ill., Benton Div., filed October 19, 2021). The plaintiff argues that “the Product’s ingredients are inconsistent with what consumers expect from a food identified as ‘shortbread cookies’” and asserts that “Dictionary.com defines shortbread as a ‘a butter cookie commonly made in thick, pie-shaped wheels or rolled and cut in fancy shapes.’” Instead of butter, the plaintiff alleges, Mondelez uses “shortening provided exclusively from vegetable oils,” resulting in a cookie that “lacks the nutritional, organoleptic, and sensory attributes of shortbread.” Further, the consumer argues, the representation of Lorna Doone cookies as providing a “Melt in Your Mouth’ taste is false and misleading” because “vegetable oils do not melt at mouth temperature, and leave a waxy mouthfeel,” while “[b]utter melts at mouth temperature and does not contribute to a waxy sensation.” The complaint also asserts that “[s]hortbread cookies made with the expected ingredients are not a rare or pricy delicacy that would make a reasonable consumer ‘double check’ to confirm the presence of butter by scouring the packaging.” The plaintiff alleges misrepresentation, fraud, unjust enrichment and violations of Illinois consumer-protection statutes.

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## MEDIA COVERAGE

# UK-US Regulatory Differences Explored Through Lens of Sprinkles

Several publications have detailed the story of Get Baked, a U.K. bakery, to examine how food regulations differ in the United Kingdom and the United States. Get Baked was forced to stop selling its 12-layer chocolate cake and raspberry glazed donut cookies after a U.K. Trading Standards inspector found the desserts to be topped with sprinkles that contain a substance labeled in the United Kingdom as erythrosine, or E127, an additive only approved for use in cocktail cherries and candied cherries, according to the [BBC](#). In the United States, the substance is labeled as FD&C Red No. 3, according to [NPR](#), and is allowed in foods but was restricted for some uses in 1990 after studies purported to show that “very high doses of the color additive can cause cancer in laboratory animals.” The BBC also noted that studies have reportedly linked the additive to hyperactivity in children and an increased risk of thyroid tumors. The owner of Get Baked told the BBC that he prefers American sprinkles, noting, “British sprinkles are rubbish. They run and aren’t bake-able. The colours aren’t vibrant and they just don’t look very good.”

In a [statement](#), West Yorkshire Trading Standards said, “We stand by the advice given and would urge all food business operators, when seeking to use imported foods containing additives, to check that they are permitted for use in the UK.”

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