



FOOD & BEVERAGE SECTOR: LABELLING, REGULATION & LIABILITY

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FOOD & BEVERAGE SECTOR: LABELLING, REGULATION & LIABILITY



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John F. Johnson III works with companies to develop and implement practical and cost-effective solutions for complying with the laws administered by Food and Drug Administration (FDA), US Department of Agriculture (USDA), Customs and Border Protection (CBP) and other federal and state agencies. He works with manufacturers, distributors, brand owners, importers and retailers of food, drugs, medical devices, cosmetics and animal products to satisfy their regulatory obligations.

CD: In your opinion, what have been the key trends and developments affecting the food & beverage sector in recent months? To what extent has the coronavirus (COVID-19) crisis had an impact?

Johnson: When coronavirus (COVID-19) first

hit, Food and Drug Administration (FDA) food enforcement, including recalls, suddenly dropped off, but with the summer months FDA appears to be more active again and several recalls are taking place. Furthermore, the FDA is working to resume in-person facility inspections. A significant enforcement trend started involving importers as the FDA began actively enforcing the Foreign Supplier Verification Program (FSVP) requirement. For the first time, the FDA placed importers with no publicly known safety issues on an import ban which is called Import Alert 99-41. While on the alert, the FDA will refuse the listed products until the importer persuades the FDA that it has a compliant FSVP regime. Enforcing this ban, the FDA issued the first

import refusals for non-compliance with FSVP.

CD: Could you provide an overview of the rules and regulations currently pertaining to the marketing, advertising and labelling of food & beverage products?

Johnson: The US Department of Agriculture (USDA) proposed new regulations for the organic

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> John F. Johnson III, Shook, Hardy & Bacon LLP

food supply-chain, which will require several new entities to be certified, including importers and brokers and traders. It is critical that all parts of the supply-chain analyse the proposed rule to determine its impact on their current practices and submit comments accordingly, especially if the impact does not appear to have been contemplated by the USDA. Active engagement is critical, as the USDA is working to build the regulatory regime for the next several decades

CD: What steps should manufacturers take to improve their quality controls and processes to ensure regulatory compliance and reduce potential liability throughout a product's lifecycle?

Johnson: Manufacturers need to continue to focus on supply-chain controls. The FSVP and the USDA Organic Proposed Rule are particularly concerned about this issue. Furthermore, COVID-19 is disrupting the supply chain and practices within individual facilities. Disruptions increase the risk potential, for example of a mislabelled product, which could result in a food allergen not being appropriately declared.

CD: Looking ahead, what are your predictions for regulation of the food & beverage sector in the coming months? To what extent may we see even tighter rules on labelling and a rise in liability risk for manufacturers?

Johnson: On the FDA front, I suspect we will see more of the same. The FDA's primary focus will remain on food safety issues, such as pathogens, allergens and the Food Safety Modernization Act (FSMA). To the extent food or beverage products make COVID-19 related claims, the FDA will move swiftly to warn the company to remove the claims. If the company does not, the FDA may consider more aggressive actions like seeking an injunction against the company. (1)