



LEGISLATION, REGULATIONS & STANDARDS

FDA Announces Revised Plans for Human Foods Program

The U.S. Food and Drug Administration (FDA) has announced additional proposed changes to the Office of Regulatory Affairs (ORA) as part of its proposal to create a unified Human Foods Program (HFP), building on a proposal announced earlier this year.

On June 27, FDA Commissioner Robert Califf said in a statement that since the agency released its proposal, a cross section of agency professionals have been working to identify additional opportunities to boost operations within the new HFP and ORA. Listening to that feedback, he said the agency's thinking has "significantly broadened."

"We know that in front of us is a once-in-a-generation opportunity to unify our field work with the priorities of program offices and Centers," he said. "This is why I'm proposing a number of additional changes to ORA, including moving several of the office's laboratories and merging its current compliance functions into those of the new HFP and other agency product Centers. These proposed changes are designed to help ensure the most strategic use of resources to meet the demands of our increasingly complex public health mission."

Following recommendations from a working group and an external evaluation conducted by a panel of experts of the Reagan-Udall Foundation, FDA is proposing:

- Establishing ORA's core mission as conducting investigations, inspections and imports for all FDA-regulated products, with

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assignments planned in partnership with the HFP and other product programs or Centers. Under this proposal, the new Deputy Commissioner of Human Foods will oversee all budget and resource allocations for the entire Human Foods Program.

- Merging compliance functions currently managed within ORA into the HFP and the product Centers' existing compliance functions to streamline operations and expedite decision-making.
- Realigning ORA-managed Human and Animal Food laboratories into the HFP.
- Transitioning certain functions under the Office of Security and Emergency Management to ORA.
- Unifying state and local food safety partnership functions and certain aspects of the international food safety partnerships into an Office of Integrated Food Safety System Partnerships in the HFP.
- Reviewing support functions ORA-wide and proposing realignment of resources and personnel to support these changes.
- Prioritizing recruitment, retention and training opportunities for the agency's field-based employees.

As part of the announcement, FDA has released high-level organization charts to reflect the proposed changes. The agency also said it is considering a renaming effort for ORA to ensure the office's title is aligned with the structure and functional duties of the agency's field operations.

USDA Approves Lab-Grown Meat for Sale

The U.S. Department of Agriculture (USDA) has reportedly given approval to Good Meat and Upside Foods to put their lab-grown chicken products on the market. The agency's Food Safety and Inspection Service issued the companies grants of inspection, clearing the way for the products to be sold in the United States. Both companies announced partnerships with high-profile chefs to introduce the product to the public.

"Immediately after receiving the grant of inspection, production started for the first batch of cultivated chicken that will be sold to celebrated restaurateur and humanitarian Chef José Andrés," Good Meat announced. Upside's announcement stated, "We're thrilled to share that our cultivated chicken will soon be available to the public for the first time at San Francisco's Bar Crenn,



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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.



prepared by 3-Michelin Star chef Dominique Crenn."

USDA Announces Effort to Strengthen Substantiation of Animal-Raising Claims



As part of a multi-step effort to strengthen the substantiation of animal-raising claims, the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) will conduct a sampling project to assess antibiotic residues in cattle heading to the “raised without antibiotics market,” the agency announced.

USDA said the results will inform whether FSIS should require that laboratory testing be submitted before companies can use the “raised without antibiotics” claim on their food labeling, or start a new verification sampling program. FSIS will also issue a revised industry guideline to recommend that companies strengthen the documentation that they submit to USDA to substantiate animal-raising claims. USDA said it plans to strongly encourage the use of third-party certification to verify such claims.

The effort stems from several petitions, comments and letters USDA has received regarding voluntary marketing claims that highlight how the source animals for meat and poultry products are raised, such as “grass-fed” or “free-range.” A wide range of stakeholders have asked the agency to reevaluate its oversight of such claims, particularly, how they are substantiated, as well as the veracity of “negative” claims, such as “raised without antibiotics.”

“Consumers should be able to trust that the label claims they see on products bearing the USDA mark of inspection are truthful and accurate,” Agriculture Secretary Tom Vilsack said. “USDA is taking action today to ensure the integrity of animal-raising claims and level the playing field for producers who are truthfully using these claims, which we know consumers value and rely on to guide their meat and poultry purchasing decisions.”

LITIGATION

Post Foods, Rock Band OK Go Resolve Trademark Dispute

Cereal maker Post Foods and the rock band OK Go have agreed to settle the food company's claims that its "OK GO!" breakfast products do not infringe on the band's trademarks. *Post Foods, LLC v. OK Go Partnership*, No. 23-0110 (D. Minn., entered June 2, 2023). A federal court agreed to dismiss the lawsuit after being

notified that the parties had settled their dispute. The terms of the settlement have not been disclosed.

The suit stemmed from the band's accusation that the company violated the Lanham Act by attempting to register and use the mark OK GO! in connection with its on-the-go breakfast cereal products and cereal-based snack foods. When the company filed a trademark application with the U.S. Patent and Trademark Office in May 2022 for the mark OK GO!, the band sent it a cease-and-desist letter. The band alleged the trademark would create confusion and lead to a false association between the band and the company's products.

McCormick 'New Mexico' Chili Pods Are Not From New Mexico, Consumer Alleges

A New York man has filed a putative class action against McCormick & Co., alleging it sells peppers described as “New Mexico Chile Pods” under the El Guapo brand that are not grown in New Mexico. *Salvaggio v. McCormick & Co.*, No. 23-6334 (W.D.N.Y., filed June 18, 2023).

The plaintiff alleges in the complaint that the product is not grown and harvested in New Mexico, noting that neither El Guapo or McCormick are licensed with the New Mexico Chile Association. He additionally asserts that customs data shows McCormick and its subsidiaries import large volumes of chili peppers of the type that are often sold as “New Mexico” chili peppers, and labeling that the product is “Packed in the USA” is a hint the products were imported outside of New Mexico but packaged in the United States.

“Typically, where a seller uses language such as ‘packed’ or ‘assembled’ in the United States, it is an implicit statement that the contents are not from the United States, because otherwise it could legally state “grown/harvested/made” in the United States,” the plaintiff argued in the complaint. “New Mexico Chili is deceptively misdescriptive as a name because the Product is not grown in New Mexico.”

For his claims of violations of New York's General Business Law Sections 349 and 350 and other state consumer fraud acts, breaches of express and implied warranty, fraud and unjust enrichment, the plaintiff is seeking class certification, damages, and costs and expenses including attorney's fees.

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