

On March 18, USDA's Food Safety and Inspection Service (FSIS) published its <u>Final Rule</u> on *Voluntary Labeling of FSIS-Regulated Products with U.S.-Origin Claims* (Final Rule).

The Final Rule covers meat, poultry, and egg products. FSIS concurrently published an updated version of its *Guideline for Label Approval*, accounting for the agency's updated view and requirements for U.S.-origin claims. The Final Rule takes effect on January 1, 2026.

In announcing the new requirements, USDA Secretary Tom Vilsack <u>explained</u> that the Final Rule "ensure[s] that when consumers see 'Product of USA' they can trust the authenticity of that label and know that every step involved, from birth to processing, was done here in America."

Key Aspects of the Final Rule

- Single-ingredient products. The claims, "Product of USA," "Made in the USA," and displays of the U.S. flag may be used only if the product is derived from animals born, raised, slaughtered, and processed in the United States. If a claim regards a specific U.S. state or territory, then a product must be derived from animals born, raised, slaughtered, and processed in that state or territory.
- Multi-ingredient products. The same claims may be used only if all ingredients—whether FSIS-regulated or not—are of U.S. origin and the preparation and processing steps occurred in the United States.
- Other origin claims. Claims of U.S. origin that are not "Product of USA," "Made in the USA," or displays of the U.S. flag will require a description on the package of the preparation and processing steps that occurred in the United States. The Final Rule noted that these claims must be truthful and not misleading.
- Cultivated meat. FSIS explains in the preamble that the Final Rule's criteria will apply to cultivated meat and poultry products under FSIS's jurisdiction. FSIS intends to approve "Product of USA" and "Made in the USA" claims if the developer can adequately substantiate that all the preparation and processing steps for the cells occurred in the United States. We anticipate FSIS will provide further guidance for the cultivated meat sector with regard to U.S.-origin claims given the novelty of the production process.
- **Recordkeeping.** Establishments will be required to maintain records supporting their U.S.-origin claims. FSIS published examples of substantiation documents in its *FSIS Guideline for Label Approval*. For example, a multi-ingredient meatloaf with the claim "Made with U.S. Beef" will comply with the new regulation if the beef is from an animal born, raised, slaughtered, and processed in the United States, but the other ingredients need not have a U.S. origin.

Takeaways

- **Higher standard.** FSIS's rule places a high bar that all aspects of a product and its production must be of U.S. origin. Many other federal, state, and foreign agencies determine a product's origin based on where a "substantial transformation" of a product occurred (see, e.g., FTC's "Made in USA" rule). FSIS explained that the definition is consistent with what consumers expect of U.S.-origin claims for FSIS-regulated products.
- **Broader implications for industry.** Consumer expectations underpin FSIS's rationale for developing and publishing the Final Rule, as explained in the preamble. It follows that FSIS's Final Rule, together with FTC's "Made in USA" rule, may have a broader influence on substantiation expectations for FDA-regulated food and other consumer products.
- Stakeholder input. The Final Rule reflects FSIS's response to industry association petitions, consumer feedback, and a call for rulemaking from the Biden administration. FSIS received citizen petitions highlighting how FSIS's former labeling requirement permitted products from animals raised and slaughtered outside the United States to be labeled "processed in the US." FSIS then prepared a November 2022 Final Report, Analyzing Consumers Value of "Product of USA" Labeling Claims, which discussed a national survey finding that a majority of consumers believed that the current FSIS "Product of USA" claim was misleading. The Final Rule seeks to more accurately reflect consumers' understanding and expectations surrounding claims of U.S. origin.

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