The U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) issued Directive 7800.1 on June 21, 2023, providing further insight into the agency's inspection and verification activities for the harvesting and processing of cell-cultured meat and poultry food products. With this new directive, USDA-FSIS also clarified instructions on interagency communications, label reviews, and import/export regulations for these products. FSIS also updated Directive 5730.1, specifying certain requirements for information sharing and liaison responsibilities regarding establishments regulated by USDA-FSIS and the U.S. Food and Drug Administration (FDA). In addition, FSIS issued new Notice 31-23 regarding sampling and testing for cell-cultured meat products.

USDA-FSIS's actions come on the heels of the agency's approval of labeling and issuances of federal grants of inspection to two U.S. cell-cultured chicken manufacturers in June 2023—which also both recently received FDA "no-questions" letters finding that the companies' products "are as safe as comparable foods produced by

other methods." According to FDA Commissioner Robert Califf and the FDA's director of the Center for Food Safety and Applied Nutrition, federal agencies are "committed to supporting innovation in the food supply" and working collaboratively with USDA-FSIS in a joint regulatory framework.

This Update summarizes these new USDA-FSIS directives and discusses implications for cell-cultured meat more generally.

What Is Cell-Cultured Meat?

Cell-cultured meat, also called cultivated meat, grows in a controlled environment from cells. Broadly speaking, manufacturers take a sample from a living animal. The selected cells are then placed in a tightly controlled environment that supports their growth. Producers may also add other substances, such as protein growth factors or edible polymer scaffolds, to encourage the sample cells to develop into muscle, fat, and connective tissue. The cells multiply into many billions or trillions of cells, growing into cell-cultured meat.

Regulatory Framework for Cell-Cultured Meat and Poultry

The FDA and USDA-FSIS jointly regulate cell-cultured meat and poultry pursuant to a Formal Agreement published in March 2019. Under the agreement, the FDA oversees cell collection, cell banks, and the process of cell proliferation and differentiation for all human food made with cultured animal cells. At the point of harvest—that is, when the cultured animal cells are removed from their growth environment for further processing—USDA-FSIS oversight begins for products derived from cell lines of USDA-amenable species. Cells harvested from all other animal sources, such as most seafood and meat from nonamenable species (e.g., reindeer, elk, deer, antelope, and certain other species), remain only under FDA oversight.

Cell-cultured meat and poultry derived from cell lines of USDA-amenable species must bear a USDA mark of inspection. Consistent with the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS inspects facilities that harvest, process, package, or label cell-cultured meat.

FSIS also regulates labeling for these products and will develop new labeling requirements for cell-cultured meat products consistent with its 2021 Advanced Notice of Proposed Rulemaking (ANPR). The ANPR makes it clear that FSIS will subject labels for cell-cultured products under its purview to preapproval, similar to how FSIS currently reviews special statements and claims as a prerequisite to a company's selling, offering for sale, or otherwise distributing FSIS-inspected meat, poultry, and egg products. Pending publication of the final rule, USDA-FSIS-regulated cultured meat and poultry manufacturers must submit their labels to USDA-FSIS for preapproval. Under the Formal Agreement, facilities for cell collection and growth are subject to inspection by the FDA. In contrast, USDA-FSIS inspects facilities where cells cultured from livestock and poultry are harvested, processed, packaged, or labeled.

The New USDA Directives

The new directives provide the following:

- Cell-cultured meats are subject to the same FSIS regulatory requirements and oversight authority as conventional meat and poultry products derived from slaughter pursuant to the Federal Meat Inspection Act and the Poultry Products Inspection Act and their implementing regulations.
- For any ingredients used postharvest, or substances used preharvest that remain in the harvested cells, all such substances must be considered safe and suitable by FSIS and used in accordance with the intended use listed in 9 CFR 424.21(c) or FSIS Directive 7120.1 (Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products).
- FSIS requires review of any ingredients not listed in 9 CFR 424.21(c) or FSIS Directive 7120.1, including processing aids and combinations of ingredients only listed individually. The review process at FSIS Directive 5020.2 applies.
- FSIS inspectors will examine a facility's operations at a minimum of once per shift.
- Because USDA-FSIS and the FDA share joint responsibility for cell-cultured meat, facilities that harvest cells for cell-cultured meat are Dual Jurisdiction Establishments. Directive 5730.1 provides detailed instructions regarding the inspections applicable to these facilities.
- Cell-cultured meat or poultry food product labels must be submitted to FSIS Labeling and Program Delivery Staff for review and approval.
- Cell-cultured meat and poultry products may not be imported into the country unless FSIS has determined that the country has a regulatory food safety inspection system that is equivalent to that of the United States for the production of such products. Cell-cultured meat and poultry food products are subject to the same FSIS import and export regulations and policies as conventional meat and poultry food products.

Takeaways

Cell-cultured meat and poultry products have crossed an important milestone on their way to the market. Cell-cultured food companies need to be prepared to navigate the dual jurisdiction environment and secure all necessary regulatory approvals from both FSIS and the FDA. In addition, these products may face challenges with state-level restrictions on the labeling of meat products.

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