Good Food Institute

FACT SHEET
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Cultivated meat's regulatory pathway

The U.S. Food and Drug Administration (FDA) has completed its first-ever safety evaluation of a cultivated meat product in the United States. What does that entail and what are the next steps on cultivated meat's regulatory path to store shelves and dinner tables?

Introduction

Under a formal agreement established in 2019, FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) share oversight of cultivated meat. FDA has jurisdiction over cell collection, banking, and cultivation for all species. USDA has jurisdiction over the processing, packaging, and labeling of cultivated meat from livestock, poultry, and catfish species. FDA retains jurisdiction over the processing, packaging, and labeling of all other cultivated seafood as well as cultivated game meat.

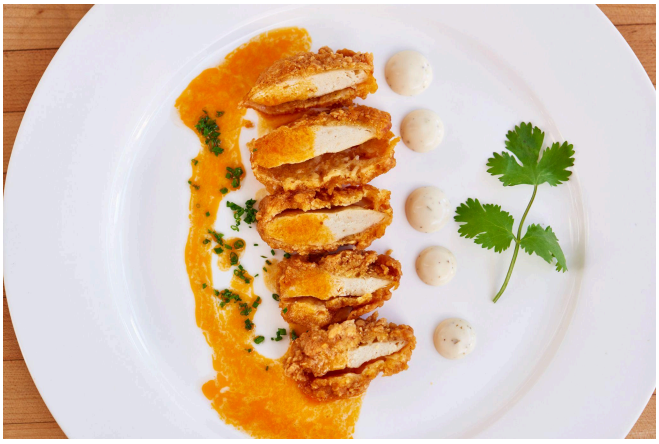

Photo courtesy of UPSIDE Foods

Premarket consultation with FDA

FDA offers a voluntary premarket consultation process for cultivated meat companies.[1] To initiate a consultation with FDA, each company must submit a range of data and information to the agency that clearly demonstrates how and why the company has determined that its product is safe for human consumption.

FDA reviews and evaluates the information provided and assesses the company's entire production process, as well as the establishment of cell lines and cell banks, proliferation and differentiation of cells, the cultivated cell material, all components and inputs, and manufacturing controls.[2] FDA may require companies to provide additional information and data as needed. Once FDA is satisfied that it has all of the necessary information and completes its evaluation, the agency informs the company that it has no further questions or concerns through a "no questions" letter.

[1] The information in this section is based on FDA's implementation of the premarket consultation process as of December 2022. FDA plans to publish guidance on this process. The information in this fact sheet is subject to change based on the substance of that forthcoming guidance.

[2] For a high-level overview of the information FDA reviewed during its first-ever premarket consultation for cultivated meat, see this FDA infographic.

FDA's response to the company, along with additional information regarding the safety evaluation, are then published on the agency's website, with any company trade secrets or proprietary commercial information redacted pursuant to existing disclosure laws.

"Food made with cultured animal cells must meet the same stringent requirements, including safety requirements, as all other food regulated by the FDA."

– FDA Press Statement, Nov. 16, 2022

FDA requirements for facility registration and manufacturing

All facilities engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States that are not exclusively regulated by USDA must register with FDA (with limited exceptions). Since cultivated meat is jointly regulated by USDA-FSIS and FDA, every cultivated meat producer will need to register its facilities with FDA (regardless of the type of product they make). Each facility must be registered before the company produces, processes, packs, or holds cultivated meat for human consumption. Such facilities must comply with FDA's current good manufacturing practice (CGMP) regulations.

In accordance with generally applicable FDA regulations, cultivated meat companies must also conduct hazard analyses and implement risk-based preventive controls. These requirements include,[3] among other things, creating and implementing a written food safety plan for each facility that includes:

- A hazard analysis that identifies potential biological, chemical, and physical hazards for each product produced
- Preventative controls to address potential hazards, including food allergen controls, sanitation controls, and supply chain controls
- Oversight, monitoring, and verification procedures
- A recall plan
- Accurate records documenting implementation of the food safety plan

FDA will conduct routine inspections at all facilities that engage in the manufacturing, processing, packing, or holding of cultivated meat. FDA will "ensure that potential risks are being managed and that biological material exiting the culture process is safe and not adulterated."

If an FDA-regulated facility is cultivating livestock or poultry cells that will later be harvested and processed in that same facility, it will also need a grant of inspection from USDA-FSIS. A facility subject to both FDA and USDA regulations must successfully complete the voluntary FDA premarket consultation process before applying for an FSIS grant of inspection. FSIS stated in its Directive 7800.1 that it will not review grant of inspection applications from establishments that harvest cells for cultivated meat products until this premarket consultation process has been completed and FDA has provided FSIS with its official findings and supporting documentation.

[3] Some smaller companies may qualify for modified food safety plan requirements, but all companies must register their facilities with FDA and implement FDA's current good manufacturing practices. Additionally, cultivated seafood producers will need to ensure compliance with FDA's seafood HACCP requirements, which differ in some ways from the food safety plan applicable to other foods.

USDA requirements for inspection and processing

Cultivated livestock, poultry, and catfish products will also be regulated by USDA-FSIS. Jurisdiction over these products will transfer from FDA to USDA at the point of harvest from the cultivator.[4] From that point, USDA inspectors will oversee processing, packaging, and labeling operations and will verify that cultivated meat products under its jurisdiction are safe, wholesome, unadulterated, and properly labeled.

Like conventional meat processing facilities, facilities that harvest, process, or pack these foods must obtain a USDA grant of inspection before producing any products for transportation or sale. Each facility will be reviewed in person and USDA will verify compliance with all applicable regulatory requirements before inspection will be granted. Generally, cultivated meat facilities will need to meet the same regulatory requirements as conventional meat facilities (other than those relating to slaughter), including facility construction specifications, written sanitation standard operating procedures, Hazard Analysis and Critical Control Point (HACCP) plans, written recall procedures, and recordkeeping requirements.

Once a facility receives a grant of inspection, USDA will conduct inspections at each facility at least once per operating shift (the same inspection rate required for conventional meat products) and regularly sample each facility's cultivated meat and poultry products.

If harvested animal cells are shipped to separate facilities for further processing, those facilities will also be overseen and inspected by USDA.[5]

Labeling

USDA has labeling jurisdiction over all cultivated livestock, poultry, and catfish products. USDA will require all cultivated product labels to be preapproved by the agency before products can be sold in restaurants and stores. USDA is currently developing regulatory requirements for labeling cultivated meat products. For now, USDA will review and approve cultivated meat labels on a case-by-case basis. As is the case for conventional meat products, all cultivated meat products offered for sale will be required to bear the official USDA mark of inspection.

FDA will have labeling jurisdiction over all cultivated seafood products, except catfish, as well as cultivated game meat. FDA is in the process of developing a framework for cultivated seafood labeling. FDA and USDA are working together to develop joint principles for labeling to ensure consistency among cultivated meat and seafood products.

Under federal law, food may not be misbranded and food labels may not be false or misleading. The agencies have stated that they will ensure that cultivated meat labels are clear, accurate, and otherwise in compliance with applicable regulatory requirements.

[4] In general, cultivated meat products will be produced by growing, differentiating, and maturing cells in a tank similar to a fermentation vat, called a cultivator. "Harvest" refers to the action of removing the material from the cultivator. After harvest, the product may undergo additional processing similar to a conventional meat product (i.e., slicing, shaping, or combining with other ingredients to create a finished food) as well as packaging for transportation and sale.

[5] Cultivated meat and poultry products are subject to the same FSIS import and export regulations and policies as meat and poultry products derived from slaughter, meaning that foreign countries are not permitted to export cultivated food products into the United States unless FSIS has determined that they have a regulatory food safety inspection system equivalent to that of the United States for the production of those products. If FSIS does make this equivalency determination about another country's cultivated meat products, it will list that country as eligible to export its product into the United States by species in the FSIS Import Library.

References

9 C.F.R. Ch. 3.

21 C.F.R. Ch. 1, Subch. B.

21 U.S.C. Ch. 9–10, 12, 27.

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About GFI

The Good Food Institute is a nonprofit think tank working to make the global food system better for the planet, people, and animals. Alongside scientists, businesses, and policymakers, GFI’s teams focus on making plant-based and cultivated meat delicious, affordable, and accessible. Powered by philanthropy, GFI is an international network of organizations advancing alternative proteins as an essential solution needed to meet the world’s climate, global health, food security, and biodiversity goals. To learn more, please visit gfi.org.