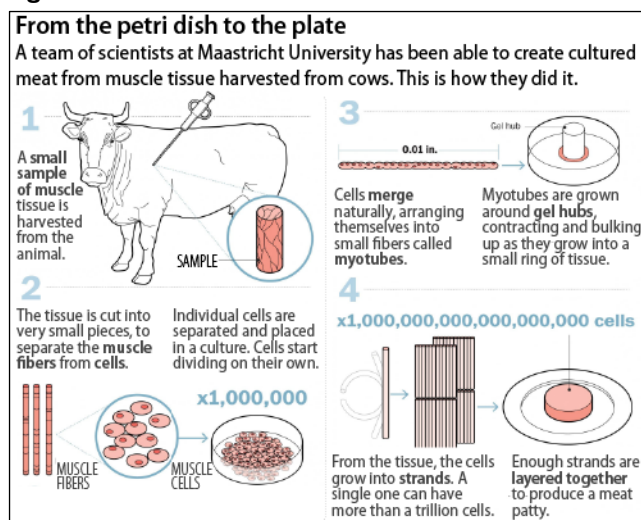


Updated October 25, 2018

## Regulation of Cell-Cultured Meat

Cell-cultured meat (also referred to as lab-grown meat, clean meat, in vitro meat, imitation meat, synthetic meat, and fake meat) is grown in laboratories from animal cell-cultures (**Figure 1**). A number of U.S. cell-cultured meat companies are developing products that some believe could be sold within three years in certain markets and widely available in 10 years. Both the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have released statements claiming oversight of cell-cultured meat (**Table 1**).

**Figure 1. Cell-Cultured Meat**



**Source:** Maastricht University, Alberto Cuadra, *Washington Post*.

### FSIS and FDA Authorities

FDA and the USDA Food Safety and Inspection Service (FSIS) ensure that the U.S. food supply—both domestic and imported—is unadulterated, wholesome, and properly labeled. For meat products, the FSIS regulates meat (amenable species: cattle, hogs, sheep, goat, and equines), poultry (chicken, turkeys, ducks, geese, squab, guinea fowl, and ratites), catfish, and egg products. FDA regulates game-meat, fish and seafood, processed meat products (containing 2%-3% of meat), and shell eggs.

FSIS implements and enforces the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA; 21 U.S.C. 1031 *et seq.*). FSIS may conduct voluntary inspections of non-amenable species (e.g., bison) under the Agriculture Marketing Act (7 U.S.C. 1621 *et seq.*).

FSIS inspection operates on the principles of Hazard Analysis and Critical Control Points (HACCP), where meat and poultry plants identify potential points of food safety

risk and develop methods to mitigate the risk. FSIS inspectors are in federally inspected meat and poultry slaughter plants during all hours of operation and in meat, poultry, catfish, and egg processing plants during each shift. During this time, inspectors are conducting food safety activities, including HACCP and sanitation checks and pathogen and residue testing.

FDA implements and enforces the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq.*), the Food Safety Modernization Act (FSMA; 21 U.S.C. 2201 *et seq.*), the Public Health Service Act (42 U.S.C. 201 *et seq.*), the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), and parts of the EPIA related to shell eggs.

FDA conducts inspections of regulated facilities to determine a firm's compliance. FDA inspections are on a periodic basis, and inspectors are not in facilities during all hours of operation. FDA also inspects vehicles and other conveyances—such as boats, trains, and airplanes—in which foods are transported or held in interstate commerce. FDA contracts with states to use their food safety agency personnel to carry out certain field inspections in support of FDA's own statutory responsibilities. FSMA provided FDA with new authorities focused on good manufacturing practices and hazard analysis and risk-based preventive controls (21 C.F.R. 117) that are designed to prevent food safety problems. FSMA provided FDA with mandatory recall authority and increased the frequency of the inspection of high-risk food facilities.

FDA and FSIS often share overlapping responsibilities for food products and have developed "memoranda of understanding" (MOU) to facilitate communication between the two agencies. For example, there are MOUs for facilities with joint jurisdiction (MOU 225-99-2001) and catfish inspection (MOU 225-14-0009).

### Cell-Cultured Meat Debate

During the first half of 2018, the livestock industry and the House Appropriations Committee addressed cell-cultured meat, while FDA and USDA each publicly staked a claim to oversight of cell-cultured meat. FDA held a public meeting in July 2018 to discuss the regulation of this new technology. USDA and FDA jointly hosted a meeting in October 2018 to discuss potential hazards in production of cell-cultured meat and labeling. Both meetings were open for public comment. (See **Table 1**.)

### Regulating Cell-Cultured Meat Production

FDA and advocates for cell-cultured meat argue that the agency is best prepared to regulate cell-cultured meat because of its expertise in regulating new food technologies and food additives. In addition, FDA's "generally recognized as safe" principles may make FDA the best

choice to regulate cell-cultured meat. Some argue that cell-cultured meat will be produced in facilities that are similar to food manufacturing or biologics facilities that FDA currently regulates, whereas cell-cultured production will not look like slaughter plants that FSIS regulates. As with traditional meat production, there are risks that cell-cultured meat could be contaminated during production stages. Either the FDA risk-based approach or the FSIS HACCP approach with regular inspector oversight could be viewed as a way to mitigate risk in cell-cultured meat production.

Some critics of cell-cultured meat argue that there is not enough information available to fully evaluate cell-cultured meat production. Friends of the Earth, an environmental advocacy group, is concerned about oversight and the safety of cell-cultured meat. In part, they raise concerns about the full disclosure of resources required to make cell-cultured meat products and the use of genetically engineered products as ingredients.

**Table 1. Timeline of Selected Events and Statements**

Date	Description
02/09/18	The U.S. Cattlemen's Association (USCA) submitted a petition to USDA asking FSIS to establish meat labeling requirements that exclude product not derived directly from animals raised and slaughtered. USDA has not responded to the petition yet.
04/18/18	During testimony before the House Committee on Appropriations, USDA Secretary Perdue, in response to questions on cell-cultured meat, stated that meat and poultry are under the sole purview of USDA and that any product labeled as meat would be under USDA purview.
05/24/18	The FY2019 House Appropriations Committee-reported USDA appropriations bill (H.R. 5961) has general provision language requiring USDA to regulate cell-cultured meat.
06/15/18	FDA Commissioner Gottlieb issued a statement on cell-cultured meat announcing that under the FFDCA, the FDA has oversight for cell-cultured meat. FDA also announced a public meeting on cell-cultured meat.
06/15/18	In response to the FDA announcement, a USDA spokesman reportedly stated that USDA has the sole purview of meat and is open to working with FDA.
07/12/18	FDA hosted a public meeting, "Foods Produced Using Animal Cell Culture Technology," where the scientific community, private sector, and advocacy groups discussed several questions that FDA posed to the public.
10/23-24/18	USDA and FDA hosted a public meeting, "The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry." USDA and FDA officials discussed respective regulatory frameworks and how they could apply to cell-cultured meat.

**Source:** Compiled by the Congressional Research Service.

### Labeling Cell-Cultured Meat Products

Besides determining how the production of cell-cultured meat will be regulated, much debate centers on what to call the product. Both FDA and FSIS are responsible for ensuring that food product labels are truthful and not misleading. The Good Food Institute (GFI), an advocacy group for plant-based foods and cell-cultured meat, argues the cell-cultured meat products should be called "clean meat." According to GFI, *clean meat* "is a more accurate way of describing real meat grown without animal slaughter. Second, 'clean meat' is similar to 'clean energy' in that it immediately communicates important aspects of

the technology—both the environmental benefits and the decrease in food-borne pathogens and drug residues." The livestock industry view the term *clean meat* as derogatory, with the inference being that if cell-cultured meat is "clean," then traditional meats would be "dirty." This could be viewed as misleading and a violation of food labeling rules. A recent *Consumer Reports* survey indicated that consumers would disagree with GFI and would prefer the "lab-grown meat" label.

Some stakeholders question whether cell-cultured meat is even "meat." The USCA petition requested that USDA limit the term *beef* to product "born, raised, and harvested in a traditional manner" and *meat* to mean the "tissue or flesh of animals that have been harvested in the traditional manner." This position would hold that cell-cultured meat should not be labeled "meat." Views among the livestock industry diverge somewhat. For example, the National Cattlemen's Beef Association (NCBA) does not support the USCA petition, although it believes the term *beef* applies only to product derived from cattle. However, NBCA believes cell-cultured meat falls under the definition of a "meat product" in FMIA—"any product ... made wholly or in part from any meat or other portion of the carcass" (21 U.S.C. 601(j)). Accordingly, cell-cultured meat—derived from animal cells—would fall under FSIS jurisdiction and oversight. The position in the USCA petition could result in FDA taking jurisdiction over cell-cultured meat.

Food labeling is often contentious. The dairy industry has long argued that the term *milk* as applied to plant-based products (e.g., almond and soy milk) is misleading and violates the FDA standards of identity for milk. Legislation introduced in the 115<sup>th</sup> Congress (Dairy Pride Act; H.R. 778 and S. 130) would limit the use of the term *milk*. In July 2018, FDA announced that it would review the labeling of plant-based "milk" and "yogurt" products.

### Unclear Regulatory Framework

In the 1980s, the White House Office of Science and Technology Policy issued the Coordinated Framework for the Regulation of Biotechnology to coordinate the roles of various agencies involved in emerging biotechnology. The agencies subsequently developed agency-specific regulations to address their oversight responsibilities.

In June 2018, *Politico* reported that the White House Domestic Policy Council would hold a meeting between FDA and USDA to discuss cell-cultured meat, indicating that the Administration could move to resolve regulatory authority issues. The Administration may need to referee decisions on how production is regulated and how it is labeled. In Congress, the House Appropriations Committee has taken the position that USDA should regulate cell-cultured meat. Others may see FDA as better suited to regulate cell-cultured meat.

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