

## A new way of approaching what's for dinner

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Households worldwide are consuming less meat. The United Nations Food and Agriculture Organization reports a steady decline in the consumption of beef products over the past 60 years. In the United States, sales of meat products at grocery stores dropped twelve percent in the past year.

Industry is taking note, as evidenced by more readily available plant-based options in supermarkets, restaurants, and fast-food chains. McDonald's recently introduced the McPlant, a plant-based burger, and even prominent meat producers, such as Tyson Foods, have introduced their own plant-based lines. Continuing to explore innovation in a once meat-driven society, companies such as Tyson have also invested in startup businesses focused on producing cultured meat from animal cells.

One report has projected that the global cell-cultured meat market could reach \$140 billion in the next decade, or about 10% of the global meat industry. While there were just a handful of cell-cultured meat startups in 2016, there currently are at least 70 worldwide. Additionally, there are approximately 40 life science companies selling cell lines and hardware that producers need to manufacture lab-grown meat.

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In simple terms, cell-cultured, or cultivated, meat is a food derived from animal cell cultures that have been harvested and grown in a lab. The process begins by removing a small amount of tissue from an animal, a process that does not permanently harm the animal. The tissue is then cut to reveal cells, which are extracted and placed in a culture containing nutrients and other factors to assist with cell multiplication. The cells then convert into primitive muscle fibers, which grow on a lattice known as "scaffolding," and eventually bulk up to form more robust muscle. Producers must then add food coloring, adipose cells, vitamins, and minerals to improve both the taste and appearance of the end product.

Cell-cultured meat proponents tout ethical, environmental, and safety advantages over traditional meat production. Specifically,

there is no slaughter involved, production uses fewer resources such as water and land, there is potentially less air pollution, and the product is grown in a lab, a controlled environment that yields less potential for contamination.

Skeptics claim that the additives needed to make the meat palatable negate the health advantages, and that the resources saved really do not amount to much. In fact, some reports have shown that the large-scale production of lab-grown meat could generate even greater concentrations of carbon dioxide over time.

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The Singapore Food Agency became the first regulatory body to approve the sale of cell-cultured meat — chicken nuggets from the company Eat Just — through a "novel food" petition. On April 22, 2021, Eat Just teamed up with Asia's leading food delivery service to launch the world's first home delivery of cell-cultured meat products. With almost no agricultural land or animals, Singapore is a natural fit for this technology and its use could lead to the island becoming a recognized meat producer.

There currently are no approved cultivated meat companies in the United States, but products are expected to appear as early as 2023. Companies are working to both scale up their processes and make the food product produced competitively priced. Tyson Foods has invested in two cultured-meat startups, Upside Foods (formerly Memphis Meats) and Future Meat Technologies. It also launched Tyson New Ventures LLC, a venture capital arm of the corporation tasked with gathering ideas from entrepreneurs to help the company meet its sustainability goals.

To address the inevitable coming to market of these products, the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) have joined forces to regulate the industry. On March 7, 2019, USDA and FDA announced a formal agreement to jointly oversee the production of cultivated meat products.

The agreement dictates that FDA will oversee the collection and growth of the cells — the production materials and processes and the manufacturing controls — using existing rules and regulations, including facility registration, Current Good Manufacturing Practices, and any other requirements applicable to substances that will become food (or components of food). USDA will oversee the cell harvest and the processing, packaging, and labeling of products.

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Collaboration between FDA and USDA is not new and makes perfect sense to address the regulation of cell-cultured meat. Specifically, shared jurisdiction, appropriately divided, will help streamline regulatory responsibilities and utilize government resources and expertise more efficiently. The agreement also ensures a checks-and-balances approach, with each agency having an opportunity to utilize its knowledge in its respective area to spot growth potential and identify and target risks.

However, in the upcoming months USDA and FDA will likely face many questions as they develop their regulatory framework. Specifically, the very definition of “meat” traditionally accepted by the two bodies could come into question.

Currently, USDA defines meat as the flesh of animals (including fish and birds) used as food that can be part of a healthful diet. FDA’s definition is similar, and its regulations define meat as part of the muscle of any cattle, sheep, swine, or goats. Do cell-cultured meat products fit within this definition? Additionally, what will be the application or approval process for these products and how long will approval take? Will manufacturers of cell lines or component materials be regulated the same way as end-product producers? How will the food products ultimately be labeled — will it be

consistent with traditional meat products or will the labels need to identify the food as cultivated? And finally, will the standards developed apply across the board to meat, poultry, and seafood products?

FDA and USDA are encouraging producers to meet with government officials early in the process as part of a premarket consultation. The hope is that the meetings will be mutually beneficial as firms make procedural decisions and the agencies draw on feedback and results obtained to implement oversight policies.

On the FDA side, the Generally Recognized as Safe (GRAS) process may be used to approve and oversee the manufacture of cell-cultured meat. The GRAS notification process in the United States is less onerous than some approval processes abroad in that premarket approval is not required.

Specifically, it is a voluntary process created to give companies a quick way to gain approval of their products. A food manufacturer can currently convene a “GRAS panel” of experts to determine if a product is GRAS. The panel can make an independent determination that the product is GRAS, or they can submit a notification to FDA with a summary of the substance, conditions of use, and basis for GRAS determination (scientific or common use). FDA will occasionally consult with USDA if the notice includes meat or poultry products.

On September 2, 2021, USDA issued an advanced notice of proposed rulemaking to solicit comments regarding the labeling of cell-cultured meat products. Importantly, USDA stated its commitment to hear from industry representatives and consider their comments when developing labeling regulations. USDA does not intend to issue any additional food safety regulations for the cultivated meat industry.

Ultimately, cell-cultured meat products will soon be available in the United States. It’s refreshing to see not only governmental bodies partnering together but also committing to work with industry to introduce high-quality, novel products to market.

### About the author



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