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# Cell-Cultivated Meat: An Overview

September 19, 2023

**Congressional Research Service**

<https://crsreports.congress.gov>

R47697



## Cell-Cultivated Meat: An Overview

Cell-cultivated meat is developed in a lab, grown from a sample of animal cells that does not require the slaughter of animals. Developing cell-cultivated meat involves five steps: (1) taking a biopsy of animal cells, (2) cell banking, (3) cell growth, (4) harvesting, and (5) food processing.

### Introduction of Cell-Cultivated Meat into the U.S. Market

The first cell-cultivated meat product developed for human consumption was created in 2013 by a scientist from Maastricht University in the Netherlands. In 2022, the U.S. Drug and Food Administration (FDA) provided premarket review and approval for two companies, GOOD Meat and UPSIDE Foods, to sell cell-cultivated chicken in U.S. markets. On June 30, 2023, the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) issued the first-ever grants of inspection to the two companies to produce cell-cultivated chicken in their facilities, and to label their products as “cell-cultivated chicken.” This was the first time that FDA and USDA regulators had approved companies to produce cell-cultivated meat products to be sold in the United States. In July 2023, UPSIDE Foods and GOOD Meat sold the first cell-cultured chicken at restaurants in San Francisco and Washington, DC, respectively. USDA and FDA are jointly regulating the production and labeling of the new food products.

### U.S. Regulation of Cell-Cultivated Meat

In February 2019, Congress directed FDA and USDA to establish a formal agreement that would delineate each agency’s responsibilities for regulating cell-cultivated meat. In March 2019, the two agencies issued an agreement outlining the regulatory roles for each agency. Under the formal agreement, FDA is to issue regulations or guidance on inspections for companies involved in cell collection, cell lines, and the differentiation process. FDA is to ensure that companies producing cell-cultivated meat products follow current Good Manufacturing Practices and preventive control regulations to ensure that the substances leaving the culturing process are safe and not adulterated. At the point of harvest, FDA transfers oversight to USDA. Companies harvesting cells for human food will be subject to FSIS regulations on sanitation, Hazard Analysis and Critical Control Point verification, and testing to ensure that the products are unadulterated, wholesome, and properly labeled under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

### The Global Market and Commercialization

More than 150 companies worldwide are involved in the cell-cultivated meat industry, 43 of which are in the United States. The United States and Singapore are the only countries that allow cell-cultivated meat products to be sold to consumers. The industry has benefitted from private and public investment in research. The Good Food Institute estimated that from 2010 to 2022, approximately \$14 billion in private capital was invested in cell-cultivated meat and seafood companies. In the last 10 years, the National Science Foundation (NSF) has issued roughly \$5 million in research grants and the USDA National Institute of Food and Agriculture (NIFA) has issued approximately \$12 million of research grants for cell-cultivated meat projects. Most of these research grants were awarded to universities. The cell-cultivated meat industry faces various hurdles in commercializing the technology, such as scaling up production, matching the taste and texture of traditional meat, and reducing the cost of finished products.

### Congressional Context

In the 116<sup>th</sup> Congress, legislation was introduced addressing cell-cultivated meat, but none was enacted. Members of Congress did not introduce bills on cell-cultivated meat in the 117<sup>th</sup> Congress or, to date, in the 118<sup>th</sup> Congress. However, two amendments submitted to the House Rules Committee for the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2024 (H.R. 4368), would prohibit the use of funds for research on cell-cultivated meat. The Rules Committee has not yet voted on a rule for H.R. 4368. Congress may or may not take any action concerning cell-cultivated meat products. If Congress chooses to act, it might consider the following policy strategies: (1) determining how federal labeling laws will interact with state labeling laws, (2) supporting federal research, and (3) setting international standards for the cell-cultivated meat industry.

This report provides an overview of the science of cell-cultivated meat, the industry, the regulatory framework for cell-cultivated meat products, congressional interests, and potential policy considerations.

R47697

September 19, 2023

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## Introduction

Cell-cultivated meat involves producing meat cells in a lab from an initial sample of animal muscle cells that do not require animals to be slaughtered.<sup>1</sup> The first cell-cultivated meat was developed for human consumption in 2013 by a scientist from Maastricht University in the Netherlands and was in the form of a ground beef burger patty.<sup>2</sup> The patty cost about \$330,000 to produce.<sup>3</sup> Since then, technological advancements have allowed scientists to produce a wide range of cell-cultivated products, including cell-cultivated beef, pork, chicken, duck, lamb, and seafood.<sup>4</sup> The major obstacles to bringing cell-cultivated meat products to the marketplace are economically producing at scale and creating a similar texture and flavor to meat produced through animal husbandry and slaughter.<sup>5</sup>

The U.S. Drug and Food Administration (FDA) provided its premarket review and approval for two companies—GOOD Meat and UPSIDE Foods—to sell cell-cultivated chicken in U.S. markets in 2022.<sup>6</sup> In June 2023, the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) issued the first-ever grants of inspection to the two companies to produce cell-cultivated chicken in their facilities, and approved the label of “cell-cultivated chicken” for their products.<sup>7</sup> In early July 2023, UPSIDE Foods sold its first cell-cultivated chicken at a restaurant in San Francisco and GOOD Meat sold its first cell-cultivated chicken in a restaurant in Washington, DC.<sup>8</sup>

This was the first time that USDA and FDA regulators had approved companies to produce cell-cultivated meat products to be sold in the United States. USDA and FDA are jointly regulating the production and labeling of the new food products.

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<sup>1</sup> Nicola Jones, “Lab-Grown Meat: The Science of Turning Cells into Steaks and Nuggets,” *Nature Journal*, vol. 619, issue 7968 (July 6, 2023), pp. 22-24, at <https://www.nature.com/articles/d41586-023-02095-6>.

<sup>2</sup> Alok Jha, “First Hamburger Made From Lab-Grown Meat to be Served at Press Conference,” *The Guardian*, August 5, 2013, at <https://www.theguardian.com/science/2013/aug/05/first-hamburger-lab-grown-meat-press-conference>.

<sup>3</sup> *Ibid.* The cost cited was €250,000, which is roughly \$330,000 at the Euro-dollar exchange rate in August 2013.

<sup>4</sup> Claire Bomkamp et al, *2022 State of the Industry Report: Cultivated Meat and Seafood*, The Good Food Institute, 2023.

<sup>5</sup> Dave Humbird, “Scale-Up Economics for Cultured Meat,” *Biotechnology and Bioengineering*, vol. 118, issue 8 (May 30, 2021), at <https://onlinelibrary.wiley.com/doi/10.1002/bit.27848>. Neil Stephens et al., “Bringing Cultured Meat to Market; Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture,” *Trends in Food Science & Technology*, vol. 78 (August 2018), pp. 155-166, at <https://www.sciencedirect.com/science/article/pii/S0924224417303400>.

<sup>6</sup> U.S. Food and Drug Administration, *FDA Completes First Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology*, Constituent Update, November 16, 2022. U.S. Food and Drug Administration, *FDA Completes Second Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology*, Constituent Update, March 21, 2023.

<sup>7</sup> The two cultivated meat plants that received FSIS “grants of inspection” on June 21, 2023, for poultry processing are the Joynn Biologics US Inc. in Richmond, CA, for GOOD Meat and the Shellmound Plant for UPSIDE Foods in Emeryville, CA. Meat processing establishments with grants of inspection are listed in the FSIS *Meat, Poultry and Egg Product Inspection Directory*, at <https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory>.

<sup>8</sup> Danielle Wiener-Bronner, “Lab-Grown Chicken Debuts in San Francisco Restaurant,” *CNN Business*, July 1, 2023, at <https://edition.cnn.com/2023/07/01/business/lab-grown-chicken-san-francisco/index.html>. Tierney Plumb, “José Andrés Is the First Chef to Serve Good Meat’s ‘No-Kill’ Chicken in the U.S.,” *EATER – Washington, DC*, July 6, 2023, at <https://dc.eater.com/2023/7/6/23785994/jose-andres-chicken-good-meat-china-chilcan>.

This report provides an overview of the industry and science of cell-cultivated meat, the regulatory frameworks for cell-cultivated meat products, and congressional interests and potential policy considerations.

## What Is Cell-Cultivated Meat?

The Food and Agriculture Organization of the United Nations (FAO) anticipates that by 2032, global consumption of meat proteins will increase, as compared with 2020-2022, from 339 million metric tons of meat protein consumed to 382 million metric tons (13% increase).<sup>9</sup> FAO attributes this potential increase in meat consumption to population growth and increased household incomes. Some researchers suggest that increasing meat production to meet the higher demand will likely result in negative environmental impacts, including increased greenhouse gas emissions, land use changes, and increased water demand.<sup>10</sup> Researchers suggest that producing cell-cultivated meat may require less land, have lower greenhouse gas emissions, and have less impact on water and land than traditional meat production.<sup>11</sup> (See “Commercialization Hurdles” for further discussion.)

Cell-cultivated meat is developed in a lab and grown from a sample of animal cells that does not require the slaughter of animals. Developing cell-cultivated meat involves five steps: (1) taking a biopsy of animal cells, (2) cell banking, (3) cell growth, (4) harvesting, and (5) food processing. (See **Figure 1** for an overview of each of these steps.) Cell-cultivated products are created uniquely from animal cells and are not analogous to plant-based meat-type products produced from plant proteins such as soybeans, peas, or nuts. A cell-cultivated meat product would not be considered a vegan or vegetarian option because it involves taking a sample of animal cells.

Currently, cell-cultivated meat is not a genetically engineered (GE) product. According to a 2020 U.S. Government Accountability Office (GAO) report, it is possible that GE tools could be used in cell-cultivated meat to target desirable traits.<sup>12</sup> The report noted that cell-cultivated meat producers would be concerned that using GE tools in cell-cultivated meat production would considerably extend the regulatory approval process and result in consumer resistance to the products.<sup>13</sup>

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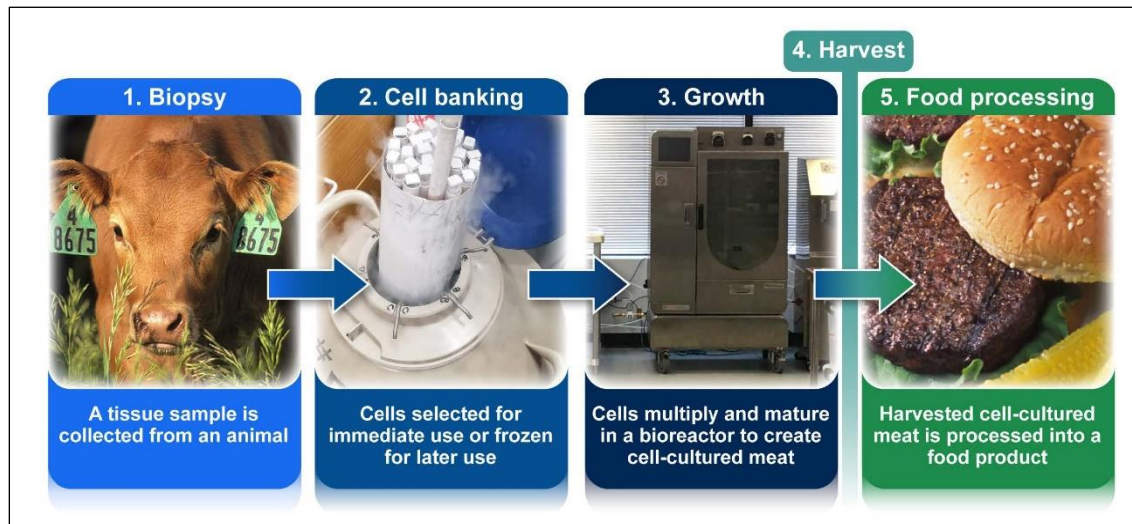
<sup>9</sup> Organization for Economic Cooperation and Development (OECD) and Food and Agriculture Organization (FAO), *OECD-FAO Agricultural Outlook 2023-2032*, OECD-FAO Report, July 6, 2023, at <https://www.oecd.org/publications/oecd-fao-agricultural-outlook-19991142.htm>.

<sup>10</sup> Natalie R. Rubio, Ning Xiang, and David L. Kaplan, “Plant-Based and Cell-Based Approaches to Meat Production,” *Nature Communications*, vol. 11, no. 6276 (December 8, 2020), at <https://www.nature.com/articles/s41467-020-20061-y>.

<sup>11</sup> Tae Kyung Hong et al., “Current Issues and Technical Advances in Cultured Meat Production: A Review,” *Food Science Animal Resources*, vol. 41, no. 3 (May 2021), at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8112310/>.

<sup>12</sup> U.S. Government Accountability Office (GAO), *FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat*, GAO-20-325, April 2020, p. 10. GAO describes desirable traits as, for example, cells that divide quickly or a greater number of times or cells that result in a reduced cholesterol or fat content.

<sup>13</sup> *Ibid.*, p. 13. Stakeholders cite the 20-year process to approve GE salmon as cause for concern about the use of GE technology.

**Figure 1. The General Process for Making Cell-Cultivated Meat**

Source: GAO and U.S. Department of Agriculture's Agricultural Research Service, GAO-20-325.

## Cell-Cultivated Meat Industry Profile

In 2022, an industry group counted 156 companies worldwide involved in the cell-cultivated meat industry.<sup>14</sup> The companies were located across six continents, with most of the companies based in the United States (n=43), Israel (n=17), the United Kingdom (n=17), and Singapore (n=12). Approximately 60% of the companies are focused on formulating and manufacturing products. The remaining companies are focused on components of the laboratory process, such as developing cell culture media, maintaining bioreactors, and optimizing ingredients.<sup>15</sup> The United States and Singapore are the only countries that allow cell-cultivated meat products to be sold to consumers. The Singapore Food Agency approved the sale of GOOD Meat cell-cultivated chicken in the country in December 2020.<sup>16</sup> FSIS provided final premarket approval to GOOD Meat and UPSIDE Foods to produce and sell cell-cultivated chicken in the United States in June 2023.<sup>17</sup>

<sup>14</sup> Claire Bomkamp et al., *2022 State of the Industry Report: Cultivated Meat and Seafood*, The Good Food Institute, 2023, at <https://gfi.org/resource/cultivated-meat-eggs-and-dairy-state-of-the-industry-report/>.

<sup>15</sup> From Larry E. Erickson, "Bioreactors," *Encyclopedia of Microbiology* (4<sup>th</sup> Ed.), 2019, pp. 536-541. Bioreactors are vessels or tanks in which whole cells or cell-free enzymes transform raw materials into biochemical products and/or less undesirable by-products. The microbial cell itself is a miniature bioreactor; other examples include shake flasks, petri dishes, and industrial fermentors. Diagnostic products based on enzymatic reactions, farm silos for silage fermentations, bread pans with fermenting yeast, and the soil in a Kansas wheat field may also be viewed as bioreactors. While a bioreactor may be simple or highly instrumented, the important consideration is the ability to produce the desired product or result. A bioreactor is designed and operated to provide an optimal environment for product formation, as selected by the scientist, baker, or winemaker. Bioreactors are key to many biotechnological systems used for agricultural, environmental, industrial, and medical applications.

<sup>16</sup> Emily Waltz, "Club-Goers Take First Bites of Lab-Made Chicken," *Nature Biotechnology*, vol. 39 (March 10, 2021), pp. 257-258, at <https://www.nature.com/articles/s41587-021-00855-1>. GOOD Meat is the cultivated meat division of food technology company Eat Just, Inc.

<sup>17</sup> GOOD Meat, "GOOD Meat Gets Full Approval in the U.S. for Cultivated Meat," press release, June 21, 2023; UPSIDE Foods, "UPSIDE is approved for sale in the US! Here's what you need to know," press release, June 21, 2023.

## Private Investment

The primary source of funding for the cell-cultivated meat and seafood industry comes from venture capital. The Good Food Institute estimated that from 2010 to 2022, approximately \$14 billion in private capital was invested in cell-cultivated meat and seafood companies worldwide. Private investments for cell-cultivated meat companies across the supply chain totaled

- \$410 million from 51 deals involving 453 unique investors in 2020;<sup>18</sup>
- \$1.3 billion from 83 deals involving 263 unique investors in 2021;<sup>19</sup> and
- \$896 million from 77 deals involving 110 unique investors in 2022.<sup>20</sup>

The biggest investment in 2022 was \$400 million for UPSIDE Foods. Some of the world's largest food and meat companies, in addition to their other investments, are investing in cell-cultivated meat companies. For example, Tyson Foods invested in UPSIDE Foods in 2018 and Believer Meats in 2021.<sup>21</sup> JBS acquired BioTech Foods in 2022 and announced the development of a cultivated meat research and development center in Brazil.<sup>22</sup> Cargill invested in UPSIDE Foods in 2017 and 2020, and invested in Aleph Farms in 2019.<sup>23</sup>

## Public Investment

Federal agencies support the cell-cultivated meat and seafood industry but at a lower level than private investors. In the last 10 years, the National Science Foundation (NSF) has issued roughly \$5 million in research grants and the USDA National Institute of Food and Agriculture (NIFA) has issued approximately \$12 million of research grants for cell-cultivated meat projects. Most of these research grants were awarded to universities.<sup>24</sup> NSF funded cultivated meat research through its Growing Convergence Research Program, Small Business Innovation Research Program, and I-Corps Program.<sup>25</sup> NIFA awarded cultivated meat research grants through its Small Business Innovation Research Program, Agriculture and Food Research Initiative, and Hatch Act funding provided to 1862 Land-Grant Institutions.<sup>26</sup>

<sup>18</sup> Madeline Cohen et al., *2021 State of the Industry Report: Cultivated Meat and Seafood*, The Good Food Institute, 2022, at <https://gfi.org/wp-content/uploads/2022/04/2021-Cultivated-Meat-State-of-the-Industry-Report-1.pdf>.

<sup>19</sup> Claire Bomkamp et al., *2022 State of the Industry Report: Cultivated Meat and Seafood*, The Good Food Institute, 2023, at <https://gfi.org/resource/cultivated-meat-eggs-and-dairy-state-of-the-industry-report/>.

<sup>20</sup> Ibid.

<sup>21</sup> Tyson Foods, "Tyson Foods Invests in Cultured Meat with Stake in Memphis Meats," press release, January 29, 2018. Memphis Meats was renamed UPSIDE Foods in May 2021. Tyson, "Tyson Ventures Announces Investment in Future Meat Technologies," press release, May 2, 2018. Believer Meats was formerly known as Future Meat Technologies.

<sup>22</sup> BioTech Foods, "BioTech Foods Grants Entry into Its Capital to JBS, the World's Largest Protein Producer," press release, January 17, 2023.

<sup>23</sup> Cargill, "Protein Innovation: Cargill Invests in Cultured Protein," press release, January 24, 2020.

<sup>24</sup> CRS searched the National Science Foundation grant database (<https://www.nsf.gov/awardsearch/>) and used the search terms "cultivated meat" and "cultured meat." CRS identified 12 research projects for a total of \$4.9 million. CRS searched the USDA Current Research Information System (<https://cris.nifa.usda.gov/>) and used the search terms "cultivated meat" and "cultured meat." CRS identified 14 research projects for a total of \$12.1 million.

<sup>25</sup> Ibid.

<sup>26</sup> Ibid. For more information concerning the National Institute of Food and Agriculture research grant programs, see CRS Report R40819, *Agricultural Research: Background and Issues*.

## Commercialization Hurdles

The cell-cultivated meat industry faces various hurdles in commercializing the technology. The primary hurdles are scaling up production, matching the taste and texture of traditional meat, and reducing the cost of finished products.

Researchers and scientists cite several issues with the current cell-cultivated technology that make it difficult to scale up production (i.e., going from developing a few sample products to show proof of concept to producing enough products to sell to grocery stores and restaurants regionally, nationally, or globally). Researchers have raised concerns about the effectiveness of bioreactors and found that they may not be as effective when used for bulk cell growth, and are likely to need retooling to keep current cell metabolism rates (i.e., how quickly energy is broken down in a cell to keep it running) when increasing the number of cells to grow.<sup>27</sup>

Scientists say one of the most difficult aspects of cell-cultivated meat production is replicating the texture of traditional meat. The current technology can generate meat muscle cells, but the cells have little shape.<sup>28</sup> Scientists are trying to incorporate plant cells to serve as scaffolding to provide the meat muscle cells with structure.<sup>29</sup> Researchers at Tufts University are developing cell-cultivated fat cells designed to improve the meat's texture and taste.<sup>30</sup>

Some researchers have explored the cost of producing cell-cultivated meat on a large-scale basis. One study estimated the wholesale cost would be \$63 to produce one kilogram (or over \$28 per pound) of cell-cultivated meat, and at retail in a supermarket or restaurant, the cost would likely be over \$100 per kilogram (or \$45 per pound).<sup>31</sup> Researchers determined that the major costs of production were the cell-culture medium, bioreactors, and highly trained labor to operate the bioreactors.<sup>32</sup> These costs account for approximately 80% of the production costs. To be able to economically scale the production of cell-cultivated meat products to make them competitively priced with conventionally produced meat, inexpensive starter cells and growth medium would be required, as well as very large bioreactors.<sup>33</sup>

Some researchers have questioned whether cell-cultivated meat and poultry production will have less of an environmental impact than conventional meat and poultry production. For example, University of California-Davis (UC-Davis) researchers assessed the life-cycle energy needs and greenhouse gas emitted throughout the production of cell-cultivated beef compared with conventionally grown beef.<sup>34</sup> According to the researchers' initial findings, "the environmental

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<sup>27</sup> Dave Humbird, "Scale-Up Economics for Cultured Meat," *Biotechnology and Bioengineering*, vol. 118, issue 8 (May 30, 2021), at <https://onlinelibrary.wiley.com/doi/10.1002/bit.27848>.

<sup>28</sup> Victoria Corless, "Plant-Based Scaffolds for Lab-Grown Meat," *Advanced Science News*, May 25, 2023, at <https://www.advancedsciencenews.com/plant-based-scaffolds-for-lab-grown-meat/>.

<sup>29</sup> Ibid.

<sup>30</sup> John Se Kit Yuen Jr. et al., "Aggregating in Vitro-Grown Adipocytes to Produce Macroscale Cell-Cultured Fat Tissue With Tunable Lipid Compositions for Food Applications," *eLife* 12:e82120, April 4, 2023; and "Lab-Grown Fat Could Give Cultured Meat Real Flavor and Texture," press release, *eLife*, April 4, 2023.

<sup>31</sup> Greg L. Garrison, Jon T. Biermacher, and B. Wade Brorsen, "How Much Will Large-Scale Production of Cell-Cultured Meat Cost?," *Journal of Agriculture and Food Research*, vol. 10 (December 2022), at <https://www.sciencedirect.com/science/article/pii/S2666154322000916>.

<sup>32</sup> Ibid.

<sup>33</sup> Lana Bandoim, "Making Meat Affordable: Progress Since the \$330,000 Lab-Grown Burger," *Forbes*, March 8, 2022, at <https://www.forbes.com/sites/lanabandoim/2022/03/08/making-meat-affordable-progress-since-the-330000-lab-grown-burger/?sh=33a1e04e4667>.

<sup>34</sup> Derrick Risner et al., "Environmental Impacts of Cultured Meat: A Cradle-to-Gate Life Cycle Assessment," *BioRxiv: Preprint Server for Biology*, April 21, 2023, at <https://www.biorxiv.org/content/10.1101/2023.04.21.537778v1.full>.



impact of cultured meat is likely to be higher than conventional beef systems, as opposed to more environmentally friendly.” The research is preliminary and has not been published in a peer-reviewed journal to date. Researchers attribute this increased environmental impact to the highly refined growth medium used in production, which is a pharmaceutical-grade medium rather than a food-grade medium. The researchers acknowledge that the technology used for cell-cultivated meat production is in its early stages, and that future technological innovations will likely be needed to scale production of cell-cultivated meat in a more environmentally sustainable fashion.

Experts in the cell-cultivated meat field have pushed back on the UC-Davis life-cycle analysis study because it assumes pharmaceutical-grade medium are being used in cultivated meat production.<sup>35</sup> According to researchers, the cultivated meat industry is moving to food-grade medium, which requires less energy to produce compared with pharmaceutical-grade medium.

Another issue for cell-cultivated meat companies is consumer acceptance of their products. A June 2023 survey found that 50% of respondents were “not very” or “not at all” interested in eating cell-cultivated meat.<sup>36</sup> Respondents said “weirdness” and “concern about food safety” were reasons for their lack of interest in trying cell-cultivated meat. UPSIDE’s Chief Operating Officer noted that many consumers are “skeptical, even squeamish” about meat produced from cells, but she has found that consumers’ attitudes change once they understand how the products are developed and are able to taste the products.<sup>37</sup>

## U.S. Regulations

### The Debate: USDA Versus FDA

From February 2018 to February 2019, stakeholders, Congress, FDA, and USDA debated whether FDA or USDA had the authority to regulate cell-cultivated meat products. In February 2018, the United States Cattlemen’s Association (USCA) submitted a petition to USDA asking that the Food Safety Inspection Service (FSIS) establish meat-labeling requirements that exclude products not derived directly from animals raised and slaughtered from being labeled as beef or meat.<sup>38</sup>

In April 2018 testimony before the House Committee on Appropriations, the Secretary of Agriculture stated that meat and poultry are under the sole purview of USDA, and that any product labeled as meat would fall under USDA jurisdiction.<sup>39</sup> Similarly, in May 2018 the House-reported agriculture appropriations bill—H.R. 5961—included a general provision that required

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<sup>35</sup> Casey Crown, “Here’s What We Know About Lab-Grown Meat and Climate Change,” *MIT Technology Review*, July 3, 2023, at <https://www.technologyreview.com/2023/07/03/1075809/lab-grown-meat-climate-change/>. Pelle Sinke et al., “Ex-Ante Life Cycle Assessment of Commercial-Scale Cultivated Meat Production in 2030,” *The International Journal of Life Cycle Assessment*, vol. 28 (January 12, 2023), pp. 234-254, at <https://link.springer.com/article/10.1007/s11367-022-02128-8>.

<sup>36</sup> “Few Adults Are Interested in Trying ‘Lab-Grown’ Meat,” *AP-NORC Center for Public Affairs Research*, June 21, 2023, at <https://apnorc.org/projects/few-adults-are-interested-in-trying-lab-grown-meat/>.

<sup>37</sup> Jonel Aleccia and Laura Ungar, “US Approves Chicken Made From Cultivated Cells, The Nation’s First ‘Lab-Grown’ Meat,” *Associated Press*, June 21, 2023, at <https://apnews.com/article/cultivated-meat-lab-grown-cell-based-a88ab8e0241712b501aa191cxbf6b39a>.

<sup>38</sup> U.S. Food Safety and Inspection Service, *Petition to Limit the Definition of Beef to Traditional Sources*, Petition No. 18-01, Petitioner: U.S. Cattlemen’s Association, February 9, 2018.

<sup>39</sup> U.S. Congress, House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, *FY 2019 Budget Hearing - U.S. Department of Agriculture*, 115<sup>th</sup> Cong., 2<sup>nd</sup> sess., April 18, 2018.

USDA to regulate cell-cultivated meat, but the provision was not in the enacted appropriation. General provision 736 read

For fiscal year 2018 and hereafter, the Secretary shall regulate products made from cells of amenable species of livestock, as defined in the Federal Meat Inspection Act, or poultry, as defined in the Poultry Products Inspection Act, grown under controlled conditions for use as human food, and shall issue regulations prescribing the type and frequency of inspection required for the manufacture and processing of such products, as well as other requirements necessary to prevent the adulteration and misbranding of these products.

In June 2018, the FDA Commissioner argued that FDA has the authority to regulate cell-cultivated meat. The Commissioner stated that

[u]nder the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over “food,” which includes “articles used for food” and “articles used for components of any such article.” Thus, as a starting point, both substances used in the manufacture of these products of animal cell culture technology and the products themselves that will be used for food are subject to the FDA’s jurisdiction.<sup>40</sup>

FDA held a public meeting entitled “Foods Produced Using Animal Cell Culture Technology” in July to discuss the emerging technology.<sup>41</sup>

In response to the FDA announcement, a USDA spokesman reportedly stated that

FDA’s claim of jurisdiction over food—and anything used in food—is so overly broad that it implies that USDA doesn’t have a role. According to federal law, meat and poultry inspections are the sole purview of USDA, so we expect any product marketed as “meat” to be USDA’s responsibility. We look forward to working with FDA as we engage the public on this issue.<sup>42</sup>

The National Cattlemen’s Beef Association (NCBA) also released a press statement in response to the FDA announcement. NCBA stated that FDA was disregarding the role of USDA in regulating meat under the Federal Meat Inspection Act and USDA’s “significant scientific expertise and long-standing success in ensuring the safety of all meat and poultry.” The release also noted that FDA has an important role in additives that are used in meat and poultry products.<sup>43</sup>

In June 2018, the Good Food Institute, which supports and lobbies for cell-cultivated meat, stated that “there’s room for the FDA and USDA to work together in regulating the new food technology.”<sup>44</sup>

In October 2018, FDA and USDA jointly hosted a public meeting, “The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry.” At the meeting, USDA

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<sup>40</sup> U.S. Food and Drug Administration, “Statement from FDA Commissioner Scott Gottlieb, M.D. and FDA Deputy Commissioner Anna Abram on Emerging Food Innovation, ‘Cultured’ Food Products,” press release, June 15, 2018.

<sup>41</sup> U.S. Food and Drug Administration, “Public Meeting on Foods Produced Using Animal Cell Culture Technology,” press release, July 12, 2018.

<sup>42</sup> Jerry Hagstrom, “FDA, USDA Spar Over Lab-Grown Meat,” *Hagstrom Report*, June 15, 2018.

<sup>43</sup> National Cattlemen’s Beef Association, “NCBA ‘Looks Forward’ to Public Meeting on Fake Meat,” press release, June 15, 2018.

<sup>44</sup> Chase Purdy, “The U.S. FDA Says It’s Taking the Lead on the Regulation of Cell-Cultured Meat,” *Quartz*, June 15, 2018, at <https://qz.com/1306996/the-fda-says-it-wants-to-regulate-clean-meat-products-in-the-us/>.

and FDA officials discussed respective regulatory frameworks and how they could apply to cell-cultivated meat.<sup>45</sup>

## FDA-USDA Agreement on Jurisdiction

In February 2019, Congress directed FDA and USDA to establish a formal agreement that would delineate each agency's responsibilities for regulating cell-cultivated meat (conference report accompanying the Consolidated Appropriations Act, 2019, Division B of H.Rept. 116-9 for P.L. 116-6). As a result, FDA and USDA issued a joint formal agreement outlining the regulatory roles for each agency in March 2019.<sup>46</sup> Joint regulation of food products by FDA and FSIS is not unusual. FDA and FSIS often share overlapping responsibilities for some food products and have developed memoranda of understanding to facilitate communication and division of responsibilities between the two agencies.<sup>47</sup>

Under the formal agreement, FDA is to issue regulations or guidance on inspections for companies involved in cell collection, cell lines, and the differentiation process.<sup>48</sup> FDA is to ensure that entities follow the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. §§301 et seq.), current Good Manufacturing Practices, and preventive control regulations to ensure that the substances leaving the culturing process are safe and not adulterated.

At the point of harvest, FDA transfers oversight to USDA. Entities harvesting cells for human food will be subject to FSIS regulations on sanitation, Hazard Analysis and Critical Control Point verification, and testing to ensure the products are unadulterated, wholesome, and properly labeled under the Federal Meat Inspection Act, as amended (FMIA; 21 U.S.C. §§601 et seq.), and the Poultry Products Inspection Act, as amended (PPIA; 21 U.S.C. §§451 et seq.). Throughout the cell-cultivated meat production process, the agreement affirms that FDA and USDA are to share information and collaborate on regulation.

According to GAO, FDA and USDA established three working groups to implement the agreement in June 2019.<sup>49</sup> The three working group areas are (1) premarket assessment, led by FDA; (2) labeling, led by USDA; and (3) transfer of jurisdiction, jointly led by FDA and USDA.<sup>50</sup> GAO issued a report on the agreement and made six recommendations for FDA and USDA to improve coordination of their regulatory oversight of cell-cultivated meat.<sup>51</sup> According to GAO, the two agencies have implemented four of the recommendations. USDA and FDA had expected

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<sup>45</sup> U.S. Department of Agriculture and U.S. Food and Drug Administration, *USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry*, transcripts and video, October 23-24, 2018.

<sup>46</sup> U.S. Food and Drug Administration and U.S. Department of Agriculture, *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species*, Memorandum of Understanding, March 7, 2019.

<sup>47</sup> U.S. Food and Drug Administration, *Domestic MOUs*, current as of August 2, 2023. For example, FDA and USDA have MOUs on dual jurisdiction for facilities (225-20-019) and on catfish inspection (225-14-009). As an example of joint regulatory authority, inspection of cheese pizza production falls under FDA regulatory authority, but FSIS is responsible for pepperoni pizza inspection.

<sup>48</sup> See March 7, 2019, memorandum.

<sup>49</sup> U.S. Government Accountability Office, *FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat*, GAO-20-325, April 2020, p. 20.

<sup>50</sup> *Ibid.*

<sup>51</sup> U.S. Government Accountability Office, *Recommendations for Executive Action*, GAO-20-325, May 7, 2020.

to implement the remaining two GAO recommendations in May 2023. However, as of September 2023, GAO has not determined whether the agencies have fully implemented them.<sup>52</sup>

## Regulatory Process

As outlined in the agreement, FDA and USDA jointly regulate cell-cultivated meat products based on their food safety authorities.<sup>53</sup> FDA regulates the cell development process of cell-cultivated meat production, and FSIS takes over during the food processing stage, when the cells are turned into meat and poultry products. FDA is responsible for overseeing both the cell development process and food processing for cell-cultivated seafood (see **Figure 1**).

## FDA Oversight

Cell-cultivated meat technology is complex, and production processes may vary. In general, FDA is responsible for regulating the following steps:<sup>54</sup>

1. Taking a sample of cells from the tissue of an animal that does not require harm to or death of the animal. Cells are selected, screened, and grown to make a “bank” of cells to store for later use.
2. Putting a small number of cells into bioreactors with nutrients and other materials to encourage cell growth and multiplication to billions or trillions of cells.
3. Growing the cultivated meat in the bioreactors by adding protein growth factors, scaffolding (i.e., structures for cells to grow on), and other nutrient materials to encourage cells to differentiate into different types of cells.
4. Once the cells have grown and differentiated into the desired type, harvesting the cellular material from the controlled environment for food processing. At this stage, regulatory authority transfers to USDA.

FDA uses its premarket consultation process and inspections of records and facilities to evaluate the food safety of cell-cultivated meat. FDA works with cell-cultivated meat developers on a product-by-product basis to ensure that the production process does not violate the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§301 et seq.). FDA evaluates the production process and the cell-cultivated material made by the production process, including the establishment of cell lines and cell banks, manufacturing controls, and all components and inputs.

## USDA Oversight

Regulatory authority passes from FDA to USDA’s FSIS during the harvest stage, when cultivated meat products are removed from the sealed growing environment and transferred to the food processing stage. FSIS issues “grants of inspection” for companies to process cell-cultivated meat to verify that the food processing facilities meet the FMIA and the PPIA requirements for

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<sup>52</sup> The current status of the implementation of the two remaining recommendations is available at <https://www.gao.gov/products/gao-20-325>.

<sup>53</sup> U.S. Food and Drug Administration authority is from the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§301 et seq.), the Public Health Service Act (42 U.S.C. §§201 et seq.), and the Fair Packaging and Labeling Act (15 U.S.C. §§1451 et seq.). U.S. Food Safety and Inspection Service authority is derived from the Federal Meat Inspection Act (FMIA; 21 U.S.C. §601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. §§451 et seq.).

<sup>54</sup> U.S. Food and Drug Administration, “Human Food Made with Cultured Animal Cells: The Science of Making Food with Cultured Animal Cells,” March 21, 2023, at <https://www.fda.gov/food/food-ingredients-packaging/human-food-made-cultured-animal-cells>.

sanitation, Hazard Analysis and Critical Control Points (HACCP) plans, and the facility design requirements.<sup>55</sup>

During processing, FSIS inspectors inspect cell-cultivated meat post-harvest and inspect processing facilities at least once a shift, which is similar to FSIS procedures for conventional meat and poultry processing. FSIS also inspects the labels for cell-cultivated meat and poultry to ensure the labels are truthful and not misleading. As with all meat and poultry inspected by FSIS, the labels for cell-cultivated meat and poultry products are required to receive prior approval before being affixed to packaging.<sup>56</sup>

In September 2021, FSIS issued an advance notice of proposed rulemaking seeking public comment on labeling considerations for cell-cultivated meat.<sup>57</sup> FDA published a similar request for public comment on the labeling of cell-cultivated seafood in October 2020.<sup>58</sup>

### First Approvals: UPSIDE Foods and GOOD Meat

On November 16, 2022, FDA completed its first premarket consultation with UPSIDE Foods for a cell-cultivated meat product for human consumption.<sup>59</sup> UPSIDE Foods submitted information to FDA on its process to develop cell-cultivated chicken. FDA evaluated the company's production process, including taking cells from chickens and establishing cell banks, manufacturing controls for the controlled environment, and the inputs that would be added to the controlled environment. FDA stated that "after our careful evaluation of the data and information shared by the firm, we have no further questions at this time about the firm's safety conclusion." On March 21, 2023, FDA completed its second premarket consultation for GOOD Meat on its process to develop cell-cultivated chicken.<sup>60</sup> FDA evaluated the materials submitted by GOOD Meat and determined it had no further questions about the company's safety conclusion.

After receiving premarket consultation clearance from FDA, GOOD Meat submitted information to FSIS on its demonstration plant in Alameda, CA, and its contract manufacturing partner, JOINN Biologics in Richmond, CA, for premarket review. UPSIDE Foods submitted similar

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<sup>55</sup> Hazard Analysis and Critical Control Points (HACCP) plans document where risks exist in meat and poultry processing and the methods to control the risks.

<sup>56</sup> U.S. Food Safety and Inspection Service, *Human Food Made with Cultured Animal Cells*, Regulatory Oversight, August 17, 2023, at <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells>.

<sup>57</sup> U.S. Food Safety and Inspection Service, "Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells," 86 *Federal Register* 49491, September 3, 2021.

<sup>58</sup> U.S. Food and Drug Administration, "Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information," 85 *Federal Register* 63277, October 7, 2020.

<sup>59</sup> Letter from Kristi Muldoon-Jacobs, Ph.D., acting director, Office of Food Additive Safety Center for Food Safety and Applied Nutrition, to Nicole Berzins, director, Regulatory Affairs UPSIDE Foods, Inc., November 16, 2022, at <https://www.fda.gov/media/163260/download>. FDA, *FDA Completes First Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology*, Constituent Update, November 16, 2022, at <https://www.fda.gov/food/cfsan-constituent-updates/fda-completes-first-pre-market-consultation-human-food-made-using-animal-cell-culture-technology>.

<sup>60</sup> Letter from Kristi Muldoon-Jacobs, Ph.D., acting director, Office of Food Additive Safety Center for Food Safety and Applied Nutrition, Kathryn Ang, senior manager, Regulatory Affairs GOOD Meat, Inc., March 20, 2023, at <https://www.fda.gov/media/166347/download>. FDA, *FDA Completes Second Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology*, Constituent Update, March 21, 2023, at <https://www.fda.gov/food/cfsan-constituent-updates/fda-completes-second-pre-market-consultation-human-food-made-using-animal-cell-culture-technology>.

information to FSIS for its facility in Emeryville, CA.<sup>61</sup> In June 2023, FSIS issued grants of inspection to UPSIDE Foods and GOOD Meat approving their manufacturing facilities to produce cell-cultivated meat, the last step in the premarket regulatory process.<sup>62</sup> FSIS also approved the label of “cell-cultivated chicken” to be used for the products produced in both facilities.

On July 1, 2023, UPSIDE Foods sold its first cell-cultivated chicken in the United States in Bar Crenn, a restaurant in San Francisco owned by Chef Dominique Crenn.<sup>63</sup> GOOD Meat featured its cell-cultivated chicken in China Chilcano, a restaurant in Washington, DC, owned by Chef José Andrés on July 5, 2023.<sup>64</sup>

## Labeling Cell-Cultivated Meat

Much debate has centered on the name for the technology referred to in this report as *cell-cultivated meat* technology. Reporters and scientists have referred to the technology and products it produces as lab-grown meat, in vitro meat, fake meat, cell-based meat, cell-cultured meat, and cultivated meat. Some of the early ideas for labelling the technology came from the alternative protein industry, which preferred the term “clean meat.” The livestock industry was concerned that the term “clean meat” would imply that meat produced using animal husbandry and slaughter was “dirty meat.”

Researchers have explored consumers’ preferences when it comes to labels for cell-cultivated meat.<sup>65</sup> Researchers found that consumers prefer the term “cultivated” and “cultured” rather than “cell-cultivated” and “cell-cultured” when referring to cell-cultivated meat. Researchers also found that government safety assurances showing approval by FDA or USDA on the product label were important to consumers.

In November 2022, 36 companies that are members of the Asia-Pacific Society for Cellular Agriculture signed a memorandum of understanding agreeing to use “cultivated” as the preferred English-language term for cell-cultivated products.<sup>66</sup>

In June 2023, USDA’s FSIS took the first step in approving the label to be used to describe cell-cultivated meat products sold in the United States. FSIS approved the label of “cell-cultivated chicken” to be used for the products developed by GOOD Meat and UPSIDE Foods. GOOD

<sup>61</sup> GOOD Meat, “GOOD Meat Gets Full Approval in the U.S. for Cultivated Meat,” press release, June 21, 2023, at <https://www.goodmeat.co/all-news/good-meat-gets-full-approval-in-the-us-for-cultivated-meat>.

<sup>62</sup> GOOD Meat, “GOOD Meat Gets Full Approval in the U.S. for Cultivated Meat,” press release, June 21, 2023, at <https://www.goodmeat.co/all-news/good-meat-gets-full-approval-in-the-us-for-cultivated-meat>; UPSIDE Foods, “UPSIDE is Approved for Sale in the US! Here’s What You Need to Know,” press release, June 21, 2023. For a listing of the facilities receiving a “grant of inspection,” see FSIS *Meat, Poultry and Egg Product Inspection Directory*, at <https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory>.

<sup>63</sup> Danielle Wiener-Bronner, “Lab-Grown Chicken Debuts in San Francisco Restaurant,” *CNN Business*, July 1, 2023, at <https://edition.cnn.com/2023/07/01/business/lab-grown-chicken-san-francisco/index.html>.

<sup>64</sup> Tierney Plumb, “José Andrés Is the First Chef to Serve Good Meat’s ‘No-Kill’ Chicken in the U.S.,” *EATER – Washington, DC*, July 6, 2023, at <https://dc.eater.com/2023/7/6/23785994/jose-andres-chicken-good-meat-china-chilcano>.

<sup>65</sup> Keri Szejda, Christopher J. Bryant, and Tessa Urbanovich, “U.S. and U.K. Consumer Adoption of Cultivated Meat: A Segmentation Study,” *Foods*, vol. 10, no. 5 (May 11, 2021), at <https://pubmed.ncbi.nlm.nih.gov/34064740/>.

<sup>66</sup> Kim Berry, “APAC Cellular Agriculture Announces MOU,” *Food and Drink Business*, November 2, 2022, at <https://www.foodanddrinkbusiness.com.au/news/apac-cellular-agriculture-announces-mou>.

Meat issued a statement saying that it and the industry prefer “cultivated” to “cell-cultivated” for their products.<sup>67</sup>

Some states have enacted laws that restrict the use of “meat” and associated terms, such as “hamburger” and “sausage,” to products that have been developed through raising animals and slaughtering them. These state laws may restrict how cell-cultivated meat products are labeled. See “Selected State Labeling Laws” below.

## Livestock Stakeholder Views

Livestock stakeholders have focused on the labeling of cell-cultivated meat products. In comments to FSIS on labeling, the National Chicken Council (NCC), the leading trade organization for the broiler industry, asked that FSIS require that a term such as “cell-cultured” be used on labels to differentiate products from conventional chicken. The NCC also asked that USDA establish a standard of identity for cell-cultivated products to simplify label rulemaking.<sup>68</sup> Both the National Cattlemen’s Beef Association (NCBA) and the National Pork Producers Council, national associations for the beef and pork industry, respectively, stated in comments on the labeling rule that the FSIS label should differentiate between a cell-cultivated product and product from animals.<sup>69</sup> The North American Meat Institute, a representative of the meat industry, provided similar comments to FSIS that called for differentiation and standards of identity. NAMI also noted the FSIS label approval process is adequate to regulate the claims of cultured meat.<sup>70</sup> In July 2023, NCBA members passed a directive in part stating, “Our priority is ensuring that consumers accurately know the difference between real beef and cell-cultured products through transparent and accurate labeling.”<sup>71</sup>

## Selected State Labeling Laws

Starting in early 2018, some state governments began enacting laws to govern the labeling of cell-cultivated meat products. Many of these laws prohibit the use of the term *meat* on the labels of cell-cultivated meat products, and some of these laws state that it is considered misbranding to label a cell-cultivated meat products with the term *meat*.

<sup>67</sup> GOOD Meat, “GOOD Meat Receives First-Ever USDA Label Approval for Cultivated Meat,” press release, June 14, 2023.

<sup>68</sup> National Chicken Council, *Docket No. FSIS-2020-0026: Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells*, Comments submitted to the U.S. Food Safety and Inspection Service, December 2, 2021, at [https://www.nationalchickencouncil.org/wp-content/uploads/2021/12/NCC-Comments-to-FSIS-Docket-No.-FSIS-2020-0036\\_Labeling-Cultured-Animal-Cells\\_Dec2021.pdf](https://www.nationalchickencouncil.org/wp-content/uploads/2021/12/NCC-Comments-to-FSIS-Docket-No.-FSIS-2020-0036_Labeling-Cultured-Animal-Cells_Dec2021.pdf).

<sup>69</sup> National Cattlemen’s Beef Association, *Comments of the National Cattlemen’s Beef Association on Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells*, 86 *Federal Register* 49491, Comments submitted to the U.S. Food Safety and Inspection Service, December 1, 2021, at [https://downloads.regulations.gov/FSIS-2020-0036-1135/attachment\\_1.pdf](https://downloads.regulations.gov/FSIS-2020-0036-1135/attachment_1.pdf). National Pork Producers Council, RE: Docket No. FSIS-2020-0036, “Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells.” Comments submitted to the U.S. Food Safety and Inspection Service, October 21, 2021, at [https://downloads.regulations.gov/FSIS-2020-0036-0915/attachment\\_1.pdf](https://downloads.regulations.gov/FSIS-2020-0036-0915/attachment_1.pdf).

<sup>70</sup> North American Meat Institute, *Re: Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells; Docket No. FSIS-2020-0036*, Comments submitted to the U.S. Food Safety and Inspection Service, December 2, 2021, at [https://downloads.regulations.gov/FSIS-2020-0036-1074/attachment\\_1.pdf](https://downloads.regulations.gov/FSIS-2020-0036-1074/attachment_1.pdf).

<sup>71</sup> NCBA, “Cattle Producers Direct NCBA Action on Cell-Cultured Products,” press release, July 26, 2023.

In the future, as cell-cultivated meat products enter commerce more widely, questions may arise about the potential interaction between these state laws, some of which are described below, and the federal labeling requirements.<sup>72</sup>

- **Arkansas.** H.B. 1407, enacted March 18, 2019, prohibits the labeling of cell-cultivated food as meat.<sup>73</sup>
- **Kansas.** S.B. 261, enacted on May 5, 2022, requires that alternative meat products sold in Kansas using meat terms be considered as misbranded if those products do not include a disclaimer that they do not contain meat.<sup>74</sup>
- **Kentucky.** H.B. 311, enacted on March 21, 2019, states that food made of cultivated animal tissue produced from in vitro cultivated animal cells cannot be labeled as meat or a meat product.<sup>75</sup>
- **Mississippi.** S.B. 2922, enacted on March 12, 2019, prohibits the labeling of cell-cultivated meat using meat terms.<sup>76</sup>
- **Missouri.** S.B. 627, enacted on June 1, 2018, prohibits the making of false claims of meat if the meat was not derived from the harvested production of livestock or poultry.<sup>77</sup>
- **North Dakota.** H.B. 140, enacted on March 12, 2019, states that cell-cultivated meat products cannot be labeled as meat.<sup>78</sup>
- **Oklahoma.** H.B. 306, enacted on May 19, 2020, defines meat as “any edible portion of livestock or part thereof” and declares it to be misrepresentation to label a product as meat that is not derived from harvested production of livestock.<sup>79</sup>
- **South Carolina.** H. 4245, enacted on May 16, 2019, makes it unlawful to advertise, sell, label, or misrepresent as “meat” or “clean meat” cell-cultivated meat that is not derived from harvested production livestock, poultry, fish, or crustaceans.<sup>80</sup>
- **Wyoming.** S.B. 68, enacted on January 10, 2018, prohibits the use of meat terms for the labeling, advertising, and selling of cell-cultivated meat products, and requires that cell-cultivated products be labeled as “containing cell-cultured products.”<sup>81</sup>

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<sup>72</sup> The potential interplay between federal and state requirements for cell-cultivated meat products is beyond the scope of this report.

<sup>73</sup> H.B. 1407 is available at <https://aglaw.psu.edu/wp-content/uploads/2020/05/Act501.pdf>.

<sup>74</sup> S.B. 261 is available at <https://aglaw.psu.edu/wp-content/uploads/2022/11/Kansas-2021-SB261-Enrolled.pdf>.

<sup>75</sup> H.B. 311 is available at <https://aglaw.psu.edu/wp-content/uploads/2021/06/Kentucky-An-Act-relating-to-cultured-animal-tissue.pdf>.

<sup>76</sup> S.B. 2922 is available at <https://aglaw.psu.edu/wp-content/uploads/2020/05/SB2922SG.pdf>.

<sup>77</sup> S.B. 627 is available at <https://aglaw.psu.edu/wp-content/uploads/2020/05/SB627.pdf>.

<sup>78</sup> H.B. 1400 is available at <https://aglaw.psu.edu/wp-content/uploads/2020/05/19-0356-07000.pdf>.

<sup>79</sup> H.B. 3806 is available at <https://aglaw.psu.edu/wp-content/uploads/2020/06/HB3806-ENR.pdf>.

<sup>80</sup> H. 4245 is available at [https://www.scstatehouse.gov/sess123\\_2019-2020/bills/4245.htm](https://www.scstatehouse.gov/sess123_2019-2020/bills/4245.htm).

<sup>81</sup> S.B. 68 is available at <https://aglaw.psu.edu/wp-content/uploads/2020/05/SF0068.pdf>.



## Congressional Activities

Three bills on cell-cultivated meat were introduced during the 116<sup>th</sup> Congress. Senator Cindy Hyde-Smith introduced the Cell-Cultivated Meat and Poultry Regulation Act of 2019 (S. 1056), which would have given USDA responsibility for regulating, inspecting, and labeling cell-based meat products. It also would have codified the responsibilities of FSIS and the FDA over food products developed in laboratories from animal cell cultures, by amending the FMIA and the PPIA. Also, Senator Mike Enzi and Representative Dusty Johnson introduced the Food Safety Modernization for Innovative Technologies Act (S. 3053, H.R. 5728). These bills would have provided statutory authority for joint agency jurisdiction over food intended for humans that is produced using animal cell culture technology, with FDA overseeing tissue collection, cell lines, and cell banks, and USDA regulating food derived from cell lines of livestock and poultry. The purposes of these bills have (largely) been addressed by the FDA and USDA regulations pursuant to the directions in the report for the Consolidated Appropriation Act, 2019 (H.Rept. 116-9).

The 117<sup>th</sup> Congress did not introduce bills on cell-cultivated meat, and thus far the 118<sup>th</sup> Congress has not introduced bills on cell-cultivated meat or the types of products that can be labeled as meat. However, two amendments submitted to the House Rules Committee (amendments #74 and #97) for the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2024 (H.R. 4368), would prohibit the use of funds for research on cell-cultivated meat.<sup>82</sup> At the date of publication, the Rules Committee had not voted on a rule for H.R. 4368. The House Appropriations Committee report for H.R. 4368 mentioned “cell-cultured protein.”

H.Rept. 118-124 for H.R. 4368 stated,

The Committee requests a report within 90 days of enactment of this Act outlining the pre-market consultation process for cell-cultured protein products, noting any special accommodations made to comply with the Formal Agreement and any agency plans to coordinate with its counterparts at USDA on further action regarding the same products.

On June 27, 2023, H.R. 4368 was introduced, reported from House Appropriations Committee, and placed on the Union Calendar for consideration.

## Policy Considerations

Congress may or may not take further action concerning cell-cultivated meat products. If Congress chooses to act, it might address the following policy issues.

### Labeling

FSIS stated that UPSIDE Foods and GOOD Meat can produce and sell products labeled as cell-cultivated chicken. Some state laws prohibit the use of meat terms on labels for cultivated meat products. Congress could provide guidance to FSIS on how cell-cultivated meat labels issued at the federal level should interact with state laws governing the labeling of cell-cultivated meat products.

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<sup>82</sup> U.S. House Committee on Rules, H.R. 4368, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2024, at <https://rules.house.gov/bill/118/hr-4368>.

## Federal Research

Researchers have identified certain obstacles for effectively scaling up production in the cell-cultivated meat industry: the high price and limited supply of growth medium, and the reduced effectiveness of bioreactors as they work with more cells. Congress could prioritize funding for NSF and NIFA research grant programs for projects that focus on overcoming the obstacles facing the cell-cultivated meat industry in scaling up production.

Alternatively, Congress may choose to pass legislation to prohibit funding of cell-cultivated meat research, similar to the proposed amendments to the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2024 (H.R. 4368). If that prohibition were established in law, then Congress would be unable to prioritize funding for cell-cultivated meat research through NSF and NIFA research grant programs.

## Setting International Standards

Cell-cultivated meat products are relatively new. Worldwide standards and regulations for those products have not been established. Congress could encourage the U.S. Codex Office, under administration of the USDA Trade and Foreign Agricultural Affairs Office, to jointly develop voluntary international food standards, guidelines, and codes of practice for cell-cultivated meat products under the Codex Alimentarius, or Food Code.<sup>83</sup> The Codex Alimentarius is a collection of voluntary standards, guidelines, and codes of practices that guide the production, exporting, and importing of food products and agricultural commodities.<sup>84</sup> The U.S. Codex Office works with the commission to develop recommendations, which in turn helps to foster harmonization of global food standards and ensure fair trade standards.

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<sup>83</sup> For more information on the U.S. Codex Office, see <https://www.usda.gov/sites/default/files/documents/codex-at-a-glance.pdf>.

<sup>84</sup> The Food and Agriculture Organization (FAO) and the World Health Organization (WHO) coordinate the Codex of Alimentarius Commission. The commission meets annually to review, edit, and adopt recommendations of its committees. The commission includes members from 188 countries, the European Union, and 240 intergovernmental organizations. To learn more, see <https://www.usda.gov/sites/default/files/documents/codex-at-a-glance.pdf>.

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