

HIGH STEAKS: HOW USDA INVOLVEMENT WILL SPOIL LAB-GROWN MEAT FOR AMERICANS

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Note

INTRODUCTION

In 1906, Upton Sinclair's *The Jungle* exposed the disgusting conditions of Chicago meat processing facilities and caused an uproar among the American people.¹ Now considered one of the most influential works of the twentieth century,² the novel prompted President Theodore Roosevelt to take a closer look at the meat industry, ultimately passing the Pure Food and Drug Act (PFDA) that same year and paving the way for the Food and Drug Administration (FDA) in 1930.³ Despite this success in policymaking, Sinclair, a vocal socialist, was disappointed that Americans focused almost entirely on the mere eight pages of his novel dealing with meat processing and not the true motivation behind the work—to expose the plight of the poor immigrant laborers in the processing plants and the exploitation they experienced.⁴ This self-interested hyperfocus on less than three percent of Sinclair's work, and the prompt government response thereto, highlighted Americans' reliance on meat as a dietary staple, willing to continue including it on the dinner table with a blind hope that the conditions described in *The Jungle* had been resolved.⁵ Today, Americans⁶ are facing yet another controversial meat production crossroad, one that likely would have baffled their repulsed 1906 counterparts—the rise of the cultured, or lab-grown, meat industry and claims that the meat production process has been over-sterilized.⁷

This Note examines the regulatory structure for cultured meat in the United States and the formal agreement reached between the FDA and the United States Department of Agriculture (USDA) for a cooperative approach. I argue that the USDA's role in this regulation is largely to pacify the department and

1. See UPTON SINCLAIR, *THE JUNGLE* 156–63 (1906).

2. Kate Lohnes, *The Jungle*, BRITANNICA, <https://www.britannica.com/topic/The-Jungle-novel-by-Sinclair> [<https://perma.cc/LU2U-PBK7>] (Sept. 15, 2023).

3. *Id.*

4. Lauren Coodley, *Upton Sinclair*, BRITANNICA, <https://www.britannica.com/biography/Upton-Sinclair#ref201390> [<https://perma.cc/CLD6-HRF3>] (Sept. 16, 2023).

5. See SINCLAIR, *supra* note 1, at 156–62.

6. While this Note will focus on *America's* reaction to and regulation of the cultured meat industry, its impact would likely be felt worldwide.

7. See Peter Hart, *Are We Really About to Start Eating Lab Meat?!*, FOOD & WATER WATCH (Dec. 5, 2022), https://www.foodandwaterwatch.org/2022/12/05/fda-upside-foods-lab-meat/?gclid=Cj0KCQjwuZGnBhD1ARIsACxbAVg3wTdyYRmfEls66wE0erSqALab_vPDyEjH8yw624UmbhH3bcT07owaAoY_EALw_wcB [<https://perma.cc/K225-RY6G>].

that the FDA should have sole control over the process. Part I gives a brief history of both the FDA and the USDA, exploring the regulation of traditional meat products up to this point. Part II introduces the concept of cultured meat, including how it is produced and why it is becoming an increasingly necessary option. Part III presents the proposed regulatory framework for cultured meat in the United States, with collaboration between the FDA and the USDA. Finally, Part IV argues that this collaborative approach is unnecessary given the differences between cultured meat production and traditional meat processing and that the FDA should have sole control over the process given the technologically advanced nature of cultured meat production and the restraints of the Federal Meat Inspection Act (FMIA) by which the USDA's role is governed.

I. HISTORY OF TRADITIONAL MEAT REGULATION

Despite the public outcry over the unsanitary conditions described in *The Jungle*, President Roosevelt was skeptical of the accuracy of Sinclair's claims and resented the frenzy caused by his work.⁸ After taking the time to read the novel and agreeing with some of Sinclair's claims, President Roosevelt facilitated the Neill–Reynolds Report, which described the findings of Labor Commissioner Charles P. Neill and social worker James Bronson Reynolds's investigation of the Chicago meat processing facilities described in the novel.⁹ As a result of these report findings confirming the accuracy of Sinclair's account and the public pressure for reform, President Roosevelt signed both the FMIA¹⁰ and the PFDA¹¹ into law on June 30, 1906.

The FMIA prohibits the adulteration and misbranding of meat and meat products to be sold as human food and requires that livestock be slaughtered and processed under strict sanitary conditions to be overseen by the USDA.¹² Later described as “The Peoples’ Department,”¹³ the USDA was originally created in 1862 by President Abraham Lincoln to research and oversee “agriculture, rural development, aquaculture, and human nutrition”¹⁴—a testament to the importance of agricultural development in United States

8. Lawrence W. Reed, *Of Meat and Myth*, MACKINAC CTR. FOR PUB. POL'Y (Feb. 13, 2002), <https://www.mackinac.org/4084> [<https://perma.cc/HK98-9B8K>].

9. Kristen L. Rouse, *Meat Inspection Act of 1906*, BRITANNICA, <https://www.britannica.com/topic/Meat-Inspection-Act> [<https://perma.cc/GY3Z-P3K7>] (Jun. 23, 2023).

10. Federal Meat Inspection Act of 1906, Pub. L. No. 59-382, 34 Stat. 669, 674 (codified as amended at 21 U.S.C. §§ 601–695).

11. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

12. See 21 U.S.C. §§ 602, 606(a).

13. Tom Vilsack, *Secretary's Column: "The Peoples' Department: 150 Years of USDA,"* U.S. DEPT OF AGRIC. (May 11, 2012), <https://www.usda.gov/media/blog/2012/05/11/secretarys-column-peoples-department-150-years-usda> [<https://perma.cc/DXQ9-4UK6>].

14. 7 U.S.C. § 2201.

II. WHY CULTURED MEAT?

It is estimated that early human ancestors began eating meat 2.6 million years ago.²⁴ The nutrient boost received from this dietary change has been credited for increasing the size and complexity of prehuman brains,²⁵ and changes in the amount and type of chewing required to digest meat are said to have directly contributed to the head and face shape of modern humans.²⁶ In short, the addition of meat to prehuman diets has been credited for making us human. While this may seem like the ultimate argument for a continued reliance on meat, according to science journalist and author Marta Zaraska, the “brain food” required for this evolution could have just as easily been peanut butter had it been available at the time.²⁷ Today’s market for meat is based more on cultural significance and an evolution-based craving than a biological or nutritional need for it.²⁸ In fact, studies have shown that regularly ingesting red meat increases the risk for heart disease, the leading cause of death in the United States.²⁹

Not only has red meat been shown to damage the bodies of those who partake in it, but livestock such as beef and dairy cows “account for the vast majority of agricultural methane emissions”—a greenhouse gas that, while shorter-lived than carbon dioxide, has eighty times the global warming power.³⁰ This shorter lifespan of agricultural methane suggests that the warming effects of the gas would end quickly and the damage done could dissipate if the animals involved were not continually replaced as they are now.³¹ On a global scale, the impacts of livestock farming are disproportionate to meat’s role in the human diet, with “[l]ivestock provid[ing] just 18 percent of calories consumed by humans but tak[ing] up 77 percent of global farmland.”³²

24. Jeffrey Kluger, *Sorry Vegans: Here’s How Meat-Eating Made Us Human*, TIME (Mar. 9, 2016, 3:52 PM), <https://time.com/4252373/meat-eating-veganism-evolution/>.

25. Matt Reynolds, *Did Eating Meat Really Make Us Human?*, WIRED (Jan. 27, 2022, 7:00 AM), <https://www.wired.com/story/human-evolution-meat/> [<https://perma.cc/V3VQ-2YZA>].

26. Katherine D. Zink & Daniel E. Lieberman, *Impact on Meat and Lower Paleolithic Food Processing Techniques on Chewing in Humans*, 531 NATURE 500, 502 (2016).

27. Dave Roos, *The Juicy History of Humans Eating Meat*, HIST., <https://www.history.com/news/why-humans-eat-meat> [<https://perma.cc/3JC7-PBMB>] (Aug. 24, 2023).

28. *Id.*

29. *Is Red Meat Bad for Your Heart... or Not?*, CLEV. CLINIC (Oct. 9, 2019), <https://health.clevelandclinic.org/is-red-meat-bad-for-your-heart-or-not/> [<https://perma.cc/BW9X-G28B>].

30. Joanna Foster, *Farmers, Scientists Seek Solutions to Global Warming Caused by Cows*, VITAL SIGNS, <https://vitalsigns.edf.org/story/farmers-scientists-seek-solutions-global-warming-caused-cows> [<https://perma.cc/EPJ4-AY6J>] (July 28, 2023).

31. *Treating Beef Like Coal Would Make a Big Dent in Greenhouse-Gas Emissions*, ECONOMIST (Oct. 2, 2021), https://www.economist.com/graphic-detail/2021/10/02/treating-beef-like-coal-would-make-a-big-dent-in-greenhouse-gas-emissions?utm_campaign=later-linkinbio-theeconomist&utm_content=later-31624796&utm_medium=social&utm_source=linkin.bio.

32. *Cultivated Meat Basics*, GOOD FOOD INST., <https://gfi.org/cultivated/> [<https://perma.cc/8XNB-ZT8D>].

Despite these health and environmental concerns, Americans are eating more red meat than ever, spending \$30.3 billion on beef in 2020,³³ and averaging approximately 220 pounds of meat per person, per year.³⁴ Nearly every restaurant today offers a vegan or vegetarian option on the menu, and plant-based meat options abound at the grocery store,³⁵ but there is still a stark divide between the taste and texture of these offerings and traditional meat for Americans who are not motivated by their love of animals or concern for the environment. For those who continue to eat meat because they simply enjoy the taste or view plant-based options as an attack on their way of life,³⁶ the market has lacked a desirable, realistic option—until now.

The concept of cultured, or lab-grown, meat has existed in some form for nearly a century,³⁷ but Mark Post, a Dutch physiologist, is credited with having created the first cultured meat burger in 2013.³⁸ An incredibly complex process, cultured meat, unlike its vegan alternatives, begins as cells taken from the tissue of a living, breathing animal in a manner that, unlike its traditional meat counterparts, typically leaves the animal not only alive, but practically unharmed.³⁹ More specifically, these cells must be stem cells—capable of self-renewal and differentiation, allowing continuous proliferation when well-characterized cell lines are used.⁴⁰ The cells are grown into a “bank,” which is stored until small quantities of the cells are subjected to strict monitoring and supplied with highly specific amounts of nutrients to facilitate multiplication.⁴¹ Once this multiplication has taken place, elements such as additional nutrients or protein growth factors are introduced to enable the differentiation of the cells and the assumption of characteristics of muscle, fat, or connective tissue

33. Kate Taylor, *Americans' Red Meat Obsession is Growing Stronger, with Beef Sales Skyrocketing to \$30 Billion as a 'Meat War' Looms*, BUS. INSIDER (May 3, 2021, 11:23 AM), <https://www.businessinsider.com/americans-more-beef-as-a-meat-war-looms-2021-5> [<https://perma.cc/PB3B-VN9W>].

34. Allison Aubrey, *FDA Gives Safety Nod to 'No Kill' Meat, Bringing It Closer to Sale in the U.S.*, NPR, <https://www.npr.org/sections/health-shots/2022/11/14/1136186819/cultivated-cultured-meat-healthy-climate-change> [<https://perma.cc/JS42-VEPC>] (Nov. 16, 2022, 10:29 PM).

35. See Brian Kateman, *Healthier Plant-Based Meat is on the Rise*, FORBES (May 10, 2021, 10:41 AM), <https://www.forbes.com/sites/briankateman/2021/05/10/healthier-plant-based-meat-is-on-the-rise/?sh=5037db6820fd>.

36. Joshua Specht, *American Bull*, AEON (June 4, 2019), <https://aeon.co/essays/the-story-of-american-beef-mythical-bloody-and-contested> [<https://perma.cc/YV3A-ABGT>] (“[S]ome Americans have begun to celebrate unapologetic carnivorousness as a political act.”).

37. GOOD FOOD INST., *supra* note 32.

38. See *World's First Lab-Grown Burger is Eaten in London*, BBC (Aug. 5, 2013), <https://www.bbc.com/news/science-environment-23576143> [<https://perma.cc/U2SL-QJX6>]; see also Mark Post, M.D., Ph.D., GOOD FOOD INST., <https://gfi.org/team/mark-post-m-d-ph-d/> [<https://perma.cc/DTH5-HQ6K>].

39. *Human Food Made with Cultured Animal Cells*, USDA FOOD SAFETY & INSPECTION SERV., <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells> [<https://perma.cc/MQ49-HV9Y>] (Aug. 17, 2023).

40. Elliot Swartz & Claire Bomkamp, *The Science of Cultivated Meat*, GOOD FOOD INST., <https://gfi.org/science/the-science-of-cultivated-meat/> [<https://perma.cc/UF3Z-VGJW>].

41. USDA FOOD SAFETY & INSPECTION SERV., *supra* note 39.

to resemble traditional meat.⁴² Finally, once this differentiation has taken place as desired, the material is harvested and prepared for processing as a human food product.⁴³ Unsurprisingly, this process is incredibly time consuming and expensive—Mark Post’s single cultured beef burger took an estimated \$325,000 to develop and years to produce.⁴⁴

Despite the initial sticker shock of Post’s monumental burger, companies have continued to develop and invest in cultured meat technologies, and in December 2020, Singapore restaurant 1880 became the first in the world to offer a cultured meat product to the public.⁴⁵ Made by California start-up Eat Just, the lab-grown “GOOD Chicken” was served thanks to Singapore’s position as the first country to approve cultured meat for sale.⁴⁶ While Eat Just did not disclose the cost to produce GOOD Chicken, co-founder and CEO Josh Tetrick explained that the process took about fourteen days and compared it to that of brewing beer,⁴⁷ highlighting the progress made in the ten years since Post’s burger. These improvements in the production efficiency and resulting cost reduction pave the way for the benefits of cultured meat—the taste and texture of traditional meat without the damaging environmental or health effects. The multiplication and differentiation of the stem cell lines involved in producing cultured meat could eventually negate the need for the large-scale ranching and farming operations in place solely to supply beef to the public. Because a single stem cell sample can be multiplied and used far more times than the traditional meat coming from a single cow, Mosa Meat, the Dutch company that presented Post’s burger in 2013, estimates that “it could make up to 80,000 quarter pounders from a single sample.”⁴⁸ This could allow for the production of 20,000 pounds of beef, which would have taken approximately thirty-five cows to produce traditionally,⁴⁹ while only having to contend with the methane emissions from one cow, and without even killing it—leaving open the possibility of more samples in the future. This potential eradication of large-scale beef farming is one of the many reasons cultured meat is controversial in

42. *Id.*

43. *Id.*

44. See Henry Fountain, *Building a \$325,000 Burger*, N.Y. TIMES (May 12, 2013), <https://www.nytimes.com/2013/05/14/science/engineering-the-325000-in-vitro-burger.html>.

45. Karen Gilchrist, *This Multibillion-Dollar Company is Selling Lab-Grown Chicken in a World-First*, CNBC MAKE IT (Mar. 1, 2021, 2:00 AM), <https://www.cnbc.com/2021/03/01/eat-just-good-meat-sells-lab-grown-cultured-chicken-in-world-first.html> [<https://perma.cc/833X-YEKA>].

46. See Jade Scipioni, *This Restaurant Will Be the First Ever to Serve Lab-Grown Chicken (For \$23)*, CNBC MAKE IT, <https://www.cnbc.com/2020/12/18/singapore-restaurant-first-ever-to-serve-eat-just-lab-grown-chicken.html> [<https://perma.cc/RDQ3-TKRR>] (Dec. 23, 2020, 9:40 AM).

47. *Id.*

48. *Lab-Grown Meat Could Be in Restaurants by 2021*, CBS NEWS (July 17, 2018, 10:14 PM), <https://www.cbsnews.com/news/mosa-meat-lab-grown-meat-could-be-restaurants-by-2021/> [<https://perma.cc/8PU7-3RFF>].

49. Randy Saner & Brianna Buseman, *How Many Pounds of Meat Can We Expect from a Beef Animal?*, UNIV. NEB.-LINCOLN INST. AGRIC. & NAT. RES. (Aug. 1, 2020), <https://beef.unl.edu/beefwatch/2020/how-many-pounds-meat-can-we-expect-beef-animal> [<https://perma.cc/GR5P-4YNW>].

the United States,⁵⁰ as Americans still envision the rugged cattle drives of the late nineteenth century and small-scale cattle ranching as pivotal to the American identity⁵¹—a conflation of what once was with the reality of today’s factory farming.⁵²

In addition to greatly reducing the agricultural methane emissions that come with traditional meat processing, cultured meat could also be a healthier substitute for its farm-raised alternative. The primary factor that makes specifically red meat dangerous to regularly consume is saturated fat, known to increase the risk for dreaded ailments such as Type 2 diabetes, heart disease, and some types of cancer.⁵³ Due to the degree of manipulation possible in the creation of fats within the cultured meat production process, scientists could replace the harmful saturated fats typically found in beef with inflammation-reducing, heart-disease-preventing omega-3 fatty acids.⁵⁴ This process could also allow for meat fortified with vitamin B12, and free of heme-iron and L-carnitine, shown to cause Type 2 diabetes and heart disease, respectively.⁵⁵ While this manipulation could make the meat Americans crave easier to contend with in the long term, the idea of meat grown in a lab is difficult to stomach for many, likely due to its “perceived unnaturalness”⁵⁶—a sharp contrast between the visceral slaughter and aftermath complained of in 1906 and the sterilized, highly-controlled cultured meat production process in 2023.

III. THE REGULATION OF CULTURED MEAT IN THE UNITED STATES

The USDA and FDA have, since the PFDA in 1906, shared control over guaranteeing the safety of America’s food supply, with their powers divided based on the type of food involved and the process for getting it from its natural state to that of a recognizable human food source, known as a product’s “amenability” to regulation.⁵⁷ The USDA’s jurisdiction primarily focuses on the regulation of slaughterhouses, meat and poultry processors, and processors

50. Maeve Sheehy, *No-Kill Burgers? US Firms Eye Green Light to Sell Lab-Grown Meat*, BLOOMBERG L. NEWS (Oct. 5, 2022, 4:15 AM), <https://news.bloomberglaw.com/environment-and-energy/no-kill-burgers-us-firms-eye-green-light-to-sell-lab-grown-meat> (“It’s a slap in the face to cow-calf producers and farmers across the land . . .”).

51. Specht, *supra* note 36.

52. John Flesher, *Factory Farms Provide Abundant Food, but Environment Suffers*, PBS NEWS HOUR (Feb. 6, 2020, 2:33 PM), <https://www.pbs.org/newshour/economy/factory-farms-provide-abundant-food-but-environment-suffers> [<https://perma.cc/6Q6N-TS6V>].

53. Marta Zaraska, *Is Lab-Grown Meat Good for Us?*, ATLANTIC (Aug. 19, 2013), <https://www.theatlantic.com/health/archive/2013/08/is-lab-grown-meat-good-for-us/278778/>.

54. *Id.*

55. *Id.*

56. Daniel L. Rosenfeld & A. Janet Tomiyama, *Would You Eat a Burger Made in a Petri Dish?*, 80 J. ENV’T PSYCH. 1, 2 (2022).

57. U.S. DEP’T. OF AGRIC., FSIS-GD-2007-0001, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 9 (2007).

whose food products contain small, specified percentages of meat.⁵⁸ The USDA guarantees compliance with these regulations primarily through an inspection regime through the Food Safety and Inspection Service (FSIS), whose employees check on the health of animals before they are slaughtered, ensure the sanitation of meat and poultry processing plants, and verify the correct labeling of meat products before they are distributed to retailers.⁵⁹ This relatively narrow scope of the USDA's role is contrasted to that of the FDA, which oversees essentially every other type of food and its processing.⁶⁰ While the FDA does conduct both regular and for-cause inspections of food processing facilities, these inspections are governed by the Food Safety Modernization Act (FSMA),⁶¹ which requires that the frequency of a facility's inspections be based on the risk associated with the specific foods being produced.⁶² For facilities falling under the USDA's jurisdiction, "inspectors must be at *every* regulated establishment during operating hours, regardless of risk."⁶³ These differences may seem like simple lines drawn in the regulatory sand, but they have drastic, real-world consequences. Take pizza, for example. A typical meatless cheese pizza requires FDA approval when the nutrition label is added to the box to ensure that the information included is accurate under the FFDCA.⁶⁴ If pepperoni is added to that same cheese pizza, three separate USDA inspections must now be conducted before it reaches the oven: one to ensure the sanitation of the slaughterhouse, one to inspect the facility that makes the pepperoni itself, and one to examine the facility that puts the pepperoni on the pizza, thanks to the USDA's control over food products containing more than two percent cooked meat.⁶⁵

As cultured meat has become a more realistic, and seemingly inevitable, addition to the American food market, questions have been raised about which agency, the USDA or the FDA, would regulate it given its glaring differences from traditional meat—particularly that the slaughter of living animals, the crux of the USDA's role, is not involved.⁶⁶ On March 7, 2019, the FDA and the

58. *FDA or USDA Jurisdiction?*, FDA READER (Feb. 27, 2019), <https://www.fda-reader.com/blog/fda-or-usda-jurisdiction> [<https://perma.cc/L99G-BP56>].

59. *Id.*

60. *Id.* ("If you can't positively identify how it falls under USDA jurisdiction, then it's regulated by the FDA.")

61. Food Safety and Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended at 21 U.S.C. §§ 2201–2206).

62. Brian P. Sylvester, *Clean Meat Staking Its Claim amid Regulatory Uncertainty*, FOOD SAFETY NEWS (July 1, 2018), <https://www.foodsafetynews.com/2018/07/clean-meat-staking-its-claim-amid-regulatory-uncertainty/> [<https://perma.cc/3KAQ-Q88X>].

63. Brian P. Sylvester et al., *From Petri Dish to Main Dish: The Legal Pathway for Cell-Based Meat*, 12 KY. J. EQUINE, AGRIC., & NAT. RES. L. 243, 276 (2020).

64. Daniela Galarza, *USDA vs. FDA: What's the Difference?*, EATER (Mar. 24, 2017, 1:32 PM), <https://www.eater.com/2017/3/24/15041686/fda-usda-difference-regulation> [<https://perma.cc/Q89J-578Y>].

65. *See id.*; *see also* U.S. DEP'T. OF AGRIC., *supra* note 57, at 8–9.

66. *See* Sylvester, *supra* note 62.

USDA reached a formal agreement as to how cultured meat would be regulated in the United States.⁶⁷ The agreement details the roles of both agencies in the oversight of “human food produced using animal cell culture technology, derived from cell lines of USDA-amenable species,” specifically that which is “required to bear a USDA mark of inspection.”⁶⁸ The agreement draws on the agencies’ longstanding roles in the regulation of food products and attempts to align the regulation of cultured meat in a similar manner.⁶⁹ These roles include the FDA’s responsibility over all living animals until they are slaughtered to produce human food,⁷⁰ and the United States Department of Agriculture Food Safety and Inspection Service’s (USDA-FSIS) control of regulation involving those living animals at the time of “slaughter, processing, packaging, and labeling”⁷¹ as applicable under the FMIA or the Poultry Products Inspection Act (PPIA).⁷² The agreement clearly divides the cultured meat production process between the authority of the U.S. Department of Health and Human Services Food and Drug Administration (HHS-FDA) and the USDA-FSIS, with the FDA focusing on the process prior to harvesting and the USDA taking over once all requirements to reach the harvesting stage have been met.⁷³

The agreement lists seven areas over which the FDA will have sole control, with an additional eighth category for sharing information with the USDA, beginning with “[c]onduct[ing] premarket consultation processes” to assess the procedures and materials necessary to begin the collection of cells, including consulting with the USDA-FSIS as required and authorized by law.⁷⁴ The FDA will oversee the cell collection process and the subsequent cell banks, release guidance for the individual producers, and inspect facilities as needed.⁷⁵ Continuing with the process, the FDA will also oversee the proliferation and differentiation of the cells up until harvest, at which time it will provide information to the USDA on the eligibility of the cells for processing to facilitate the transfer of oversight to the USDA.⁷⁶ After the transfer takes place, the FDA will continue to ensure the compliance of covered entities including

67. *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, U.S. FOOD & DRUG ADMIN. (Mar. 7, 2019), <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell> [https://perma.cc/HWD9-6FRB].

68. *Id.*

69. USDA FOOD SAFETY & INSPECTION SERV., *supra* note 39.

70. *Id.*

71. *Id.*

72. 21 U.S.C. §§ 451–473.

73. U.S. FOOD & DRUG ADMIN., *supra* note 67.

74. *Id.*

75. *Id.*

76. *Id.*

Current Good Manufacturing Practices⁷⁷ and facilities registration.⁷⁸ The FDA will also ensure that the processes and facilities used do not result in adulteration of the biological material produced as defined under the FFDCAs⁷⁹ and that the material is safe for human consumption.⁸⁰ The FDA will conduct follow-up activities and inspections, except for those solely under the USDA's jurisdiction, to ensure compliance with applicable FDA laws.⁸¹ Finally, the FDA is tasked with sharing information with the USDA to facilitate collaboration and a smooth transfer of oversight of the process from one agency to the other.⁸²

Beginning at harvest, the USDA will facilitate the transfer of oversight from the FDA, including reviewing data collected by the FDA as to the eligibility of the harvested material to be further processed into a human food product that will bear the USDA seal of inspection.⁸³ The USDA will further ensure that the facilities harvesting the resulting biological material are in compliance with the FMIA or PPIA, mainly in that they have received a grant of inspection from the USDA.⁸⁴ The USDA will conduct inspections of the facilities where the cells are "harvested, processed, packaged or labeled," particularly ensuring compliance with sanitation requirements and ensuring that the material has not become adulterated throughout the process.⁸⁵ The USDA will ensure that the labeling of the material is preapproved and verified as required by the FSIS.⁸⁶ The USDA is also tasked with developing additional requirements based on the FMIA and PPIA to ensure the safety of the cultured meat produced, as well as the accuracy of its labeling.⁸⁷ Finally, the USDA is responsible for enforcement actions to guarantee that any cultured meat that has been adulterated or mislabeled does not reach the public, and for continuing to share information with the FDA pertaining to the process and how it can be improved.⁸⁸

IV. ARGUMENTS FOR SOLE FDA CONTROL

In the resulting vague outline of cultured meat regulation in the United States, the FDA oversees the entirety of the creation of the meat itself, and the

77. *FSMA Final Rule for Preventive Controls for Human Food*, FDA, <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food> [<https://perma.cc/X9FB-UHC3>] (July 13, 2023).

78. U.S. FOOD & DRUG ADMIN., *supra* note 67.

79. 21 U.S.C. § 342.

80. U.S. FOOD & DRUG ADMIN., *supra* note 67.

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

USDA takes over once the process is essentially over and the meat is ready to be harvested.⁸⁹ Since this agreement was reached in 2019, the FDA deemed “food made from cultured chicken cells” produced by UPSIDE Foods to be safe for human consumption on November 16, 2022.⁹⁰ Just over four months later, the FDA also issued a “no questions” letter to GOOD Meat on March 20, 2023, deeming the cultured meat originally sold in Singapore a possibility for Americans.⁹¹ While once a major hurdle for cultured meat producers in the United States, under the current regulatory regime, FDA approval does little to get these products on grocery store shelves or restaurant menus without a nod from the USDA.⁹² Fortunately, and somewhat surprisingly, lab-grown chicken from both UPSIDE Foods and GOOD Meat was approved by the USDA for sale on June 21, 2023.⁹³ Even with these two companies cleared to produce and sell their cultured meat in the United States, this initial acceptance by the USDA does little to calm anxieties surrounding the efficiency and overall effectiveness of the current regulatory structure, and the time between FDA and USDA approval for both of these companies highlights the USDA’s power to delay progress in this new and undoubtedly fragile industry.

While the FDA’s role in the cultured meat production process is rational given the breadth of its authority over the nation’s food supply as a whole, the USDA’s involvement is redundant given the differences between this process and that of processing traditional meat. The FDA’s oversight of the highly technical and scientifically involved process of converting single animal cells to recognizable meat is logical given the agency’s experience regulating “emerging food technologies,” such as “genetically modified organisms (GMOs), genetically engineered animals, and cloning.”⁹⁴ Especially relevant, the FDA also has experience with other cell-cultured technologies in both the medical and nutrition realms.⁹⁵ While the USDA’s role in inspecting the facilities involved in the production of cultured meat and ensuring compliance with the relevant regulations is not surprising given the prevalence of inspections in the regulation of traditional meat, these inspections are primarily to seek out and

89. *Id.*

90. *FDA Spurs Innovation for Human Food from Animal Cell Culture Technology*, FDA (Nov. 16, 2022), <https://www.fda.gov/news-events/press-announcements/fda-spurs-innovation-human-food-animal-cell-culture-technology> [https://perma.cc/BH39-6U8S].

91. Allison Aubrey, *FDA Gives 2nd Safety Nod to Cultivated Meat, Produced Without Slaughtering Animals*, NPR (Mar. 21, 2023, 5:41 PM), <https://www.npr.org/sections/health-shots/2023/03/21/1165071880/fda-gives-2nd-safety-nod-to-cultivated-meat-produced-without-slaughtering-animal> [https://perma.cc/NVK5-9C4Z].

92. *Id.*

93. Jonel Aleccia & Laura Ungar, *US Approves Chicken Made from Cultivated Cells, the Nation’s First ‘Lab-Grown’ Meat*, ASSOCIATED PRESS (June 21, 2023, 10:23 AM), <https://apnews.com/article/cultivated-meat-lab-grown-cell-based-a88ab8e0241712b501aa191cdbc6b39a> [https://perma.cc/CF4D-7W4G].

94. Jaden Atkins, Note, *Regulating the Impending Transformation of the Meat Industry: “Cultured Meat,”* 24 J. TECH. L. & POL’Y 1, 6 (2020).

95. *Id.*

prevent contamination and adulteration,⁹⁶ and in the cultured meat context, these issues would likely only arise in the laboratory over which the FDA has regulatory oversight.⁹⁷ Additionally, while contamination is always possible during or after harvest, the FDA has the capacity and the experience to conduct contamination and adulteration-focused inspections of the cultured meat process given its experience conducting these inspections over the production of every food product not covered under the FMIA or PPIA.⁹⁸

Compared to the traditional role of the USDA, the agreement seems to suggest that harvesting the newly produced cultured meat is analogous to slaughter in traditional meat production.⁹⁹ Under the FMIA, a “meat food product” is defined as “any product capable of use as human food which is made wholly or in part from any meat or other portion of the *carcass* of any cattle, sheep, swine, or goats.”¹⁰⁰ This definition suggests that the USDA’s authority over the meat inspection process requires, or is based around, the *death* of an animal, with rationale for the oversight being the increased risk of bacterial contamination from the difficulty in regulating temperatures and contact with contaminated surfaces, increasing the risk for food poisoning and other illnesses upon consumption.¹⁰¹ Aside from the fact that cultured meat production eliminates the involvement of an animal carcass in the process, this risk of contamination is greatly reduced by the sterile laboratory environment and techniques used to produce cultured meat.¹⁰² Additionally, the possibility of producing large quantities of cultured meat from a miniscule sample of animal cells allows for producers to be more selective in the specific animals used for the process—eliminating the often-denied practice of using “downed” cows, those that are too sick or injured to walk to the processing stage, for meat.¹⁰³

In reality, the step most analogous to slaughter in cultured meat production would likely be that of initially obtaining the cells from the animal, in that both processes facilitate the production and processing of meat, and the process of obtaining the cells is likely to require protocol to guarantee humane methods,

96. 21 U.S.C. § 602.

97. Tammi S. Etheridge, *What’s the Beef? The FDA, USDA, and Cell-Cultured Meat*, 79 WASH. & LEE L. REV. 1729, 1757 (2022).

98. See Michael Mezher, *FDA Says It Far Exceeded Its Projections for Inspections in FY2021*, REGUL. FOCUS (Nov. 22, 2021), <https://www.raps.org/news-and-articles/news-articles/2021/11/fda-says-it-far-exceeded-its-projections-for-inspe> [<https://perma.cc/U79H-XH7P>].

99. See U.S. FOOD & DRUG ADMIN., *supra* note 67.

100. 21 U.S.C. § 601(j) (emphasis added).

101. See *Foods That Can Cause Food Poisoning*, CTR. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/foodsafety/foods-linked-illness.html> [<https://perma.cc/W9EC-LX8N>] (Aug. 9, 2023).

102. Etheridge, *supra* note 97, at 1779.

103. Matthew L. Wald, *Meat Packer Admits Slaughter of Sick Cows*, N.Y. TIMES (Mar. 13, 2008), <https://www.nytimes.com/2008/03/13/business/13meat.html>.

as is the case with traditional slaughter now under the FMIA.¹⁰⁴ If the USDA, in its contamination and adulteration preventing capacity,¹⁰⁵ is meant to be involved in the cultured meat production process, it makes more sense for its involvement to begin at the moment when the cells are taken from the living animal, likely to involve the potential of contamination even with the most rigorous sanitary measures in place, than at the moment of harvest from a sanitary lab as the agreement mandates currently.¹⁰⁶ It is also at this point when the process most closely resembles the natural, biological focus associated with the United States Department of *Agriculture*, as illustrated by the USDA's authority over organic food labeling¹⁰⁷ compared to the FDA's authority over GMOs,¹⁰⁸ and not after the cells have been manipulated in a laboratory environment.

Not only does the USDA's role in regulating cultured meat seem to be an appeasement of the USDA based on its longstanding role in meat regulation, rather than a necessary safeguard for consumers, but the prospect of regulating cultured meat consumption may be a conflict of interest for the USDA.¹⁰⁹ The Agricultural Marketing Service (AMS) is one of the primary agencies under the USDA, tasked with "promoting and ensuring the livelihoods of farmers, ranchers, and producers."¹¹⁰ Prior to being absorbed by the AMS, the Grain Inspection, Packers, and Stockyards Administration (GIPSA) expressed concerns over the future of the meat industry, "includ[ing] plant-based and lab-created proteins in its list of industry concerns."¹¹¹ While cultured meat may be the protein source of the future, it is undeniable that even if it makes its way onto every dinner table in the United States, the livestock farming and ranching industry will suffer, largely due to the fact that a fraction of the animals would be necessary to feed the masses. Michael Taylor, former head of the FSIS, explains that the USDA has a "cozy relationship [with] the meat industry," going as far as to say that in his experience, decades of lobbying resulted in "the USDA thinking of the industry as the customer rather than the consumer."¹¹² What motivation does the USDA have for diligently regulating and promoting a new protein source that directly harms an industry with which it has this longstanding, beneficial relationship? Even if the meat itself survives the

104. 21 U.S.C. § 603(b).

105. *Id.* § 603(a).

106. U.S. FOOD & DRUG ADMIN., *supra* note 67.

107. *Organic Regulations*, USDA AGRIC. MKTG. SERV., <https://www.ams.usda.gov/rules-regulations/organic> [<https://perma.cc/68K9-P3WE>].

108. *How GMOs Are Regulated in the United States*, FDA, <https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-united-states> [<https://perma.cc/9DU5-MEYA>] (Apr. 19, 2023).

109. Etheridge, *supra* note 97, at 1763.

110. *Id.* at 1767.

111. *Id.* at 1768.

112. Steve Johnson, *The Politics of Meat*, PBS FRONTLINE, <https://www.pbs.org/wgbh/pages/frontline/shows/meat/politics/> [<https://perma.cc/RTZ5-JZL8>].

production process with both FDA and USDA oversight, what is stopping the USDA from being more stringent in its inspections of facilities known to process cultured versus traditional meat, thus limiting or preventing its success?

By its very nature and the limits of the FMIA and PPIA, the USDA has a narrow scope of control over America's food supply, particularly compared to the FDA.¹¹³ The conflict-of-interest concerns surrounding the USDA's role in cultured meat production do not exist for the FDA because the success of cultured meat does not threaten the FDA's authority and structure in the same way that it does the USDA's. Even if the USDA does maintain its role in cultured meat regulation and it goes on to replace traditional meat as we know it, the farmers and ranchers the USDA has been described as having a cozy relationship with will be left largely jobless, thus likely prompting the USDA to limit the success of cultured meat long before it reaches this point. The FDA does not have these same forces working against the success of cultured meat. If cultured meat is successful, the FDA adds to the laundry list of foods it is already in charge of regulating. If cultured meat never becomes more to the United States than a story about cultured chicken served in Singapore, the FDA essentially loses nothing and is left where it started, regulating the foods not specifically granted to the USDA in the FMIA and PPIA. The ultimate success, and survival, of cultured meat in the United States rests on the USDA's willingness to play fair, an unlikely outcome given its open hostility toward traditional meat alternatives in the past.¹¹⁴

CONCLUSION

Despite dramatic differences in technology, Sinclair's readers and Americans today have a lot in common—a focus on the impact of meat production to their own diets over the impacts of the meat industry on society and its ability to thrive, harming the planet and the people who call it home. Cultured meat has the potential to mitigate much of the damage done by America's reliance on traditional meat, decreasing the impacts of harmful agricultural methane and reducing rates of heart disease and Type 2 diabetes. While the United States has taken steps to prepare for the oncoming wave of the cultured meat market, the current structure splitting authority between the FDA and USDA is unnecessary. The FDA is capable of overseeing the entire process, and the timing of the USDA's entry into the process suggests its inclusion is merely to pacify an agency that feels it is being left behind. This regulatory structure should be amended to give the FDA sole authority, leaving

113. See Erica Bakota, *FDA vs. USDA: What's the Difference?*, GOVLOOP (Aug. 22, 2019), <https://www.govloop.com/community/blog/fda-vs-usda-whats-the-difference/> [<https://perma.cc/NKP9-BKE2>].

114. See Etheridge, *supra* note 97, at 1768.

the USDA to focus on the traditional meat industry and the slaughter of the animals it involves.

*Kaylee Hall**

* Juris Doctor Candidate (May 2024), The University of Alabama School of Law. Thank you to my friends and family for their love and support throughout my time in law school (and for putting up with my lifelong picky eating habits that served as the inspiration for this Note). I would also like to thank the editors of Volume 75 of the *Alabama Law Review* for their diligent work in getting this Note ready for publication.