The Meat of the Matter: Regulating a Laboratory-Grown Alternative

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ABSTRACT

As consumer demand for meat increases and available land decreases, alternative options like laboratory-grown meat become more appealing. Companies like Memphis Meats and Mosa Meat hope to stock grocery store shelves with their lab-grown meat products within the next five years. Investors have recently shown their avid interest in the concept, particularly for environmental, public health, and animal welfare reasons. But American meat trade associations and lobbying groups are expressing concern about how such a new product will be regulated. This paper explains the need for lab-grown meat and the basic science behind its creation. It explores whether the Federal Food, Drug, and Cosmetic Act (FDCA) or the Federal Meat Inspection Act (FMIA) would be a more appropriate regulatory tool. This paper ultimately advocates that the United States Department of Agriculture, rather than the Food and Drug Administration, is the proper regulator.

INTRODUCTION

In 1932, Winston Churchill predicted that within fifty years, "[w]e shall escape the absurdity of growing a whole chicken in order to eat the breast or wing, by growing these parts separately under a suitable medium."[1] While his prediction did not come true in 1982, it may well come true by 2022.

Imagine that the hamburger you eat for lunch does not require the slaughter of a cow. Imagine that the duck à l'orange from that fancy downtown restaurant and the Southern chicken sandwich from the local grocer did not involve the death of any poultry. What if meat production occurs in a building rather than sprawling warehouses or acres of pasture? Paul McCartney says that if slaughterhouses had glass walls, everyone would be vegetarian.[2] But what if "slaughterhouses" looked like sleek metal machines and offered public tours, similar to a brewery?

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1 Winston Churchill, *Fifty Years Hence* (1932), http://rolandanderson.se/Winston_Churchill/Fifty_Years_Hence.php.

2 *See, e.g.*, *Glass Walls* (People for the Ethical Treatment of Animals 2013), https://www.youtube.com/watch?v=ql8xkSYvwJs.

These are the goals of companies like Memphis Meats[3] and Mosa Meat.[4] Innovative investors, scientists, and entrepreneurs[5] are starting to realize that meat grown in a laboratory may be better for the environment, animal welfare, and human health. Known by many names—"lab-grown meat," "in vitro meat," "clean meat," "cultured meat"—this phenomenon has gained traction over the last decade to the point where it is now necessary for the law to get involved.

This paper provides background on the main way that meat is currently produced in the United States. Then, the process of creating lab-grown meat is described, with a discussion of the key players and investors in this developing field. Finally, an analysis of which federal agency should regulate lab grown meat and suggestions for how existing law may be applied. Ultimately, this paper argues that the United States Department of Agriculture is the proper regulator under its Federal Meat Inspection Act authority. Lab-grown meat is the way of the future, and American law should accommodate accordingly.

I. MEAT PRODUCTION IN THE UNITED STATES

Traditionally, meat in the United States originated from family-run farms that grew both animals and crops.[6] However, during the twenty-first century, global demand for meat, dairy, and poultry products increased by over one hundred percent, with another projected rise of seventy-three percent by 2050.[7] New technologies such as computerized irrigation, synthetic herbicides, and genetically modified organisms have developed.[8] These technologies have enabled quicker and better-quality results with less manpower. Small farms consolidated to form bigger conglomerates.[9] In 2012, the United States Department of Agriculture (USDA) census revealed that farms with $1 million or more in annual sales, which account for only four percent of total U.S. farms, produce a whopping two-thirds of the country's agricultural output.[10] The image of an idyllic family-run farm is a relic of the past. This section describes how the new type of farm impacts the environment, economy, and public health.

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3 *About Us*, MEMPHIS MEATS, http://www.memphismeats.com.

4 *Mission and Vision*, MOSA MEAT, http://mosameat.eu/index.html.

5 *See, e.g.*, Josh Schonwald, *The Frankenburger is Coming Sooner Than You Think Thanks to Google*, TIME MAG. (Aug. 15, 2014), http://time.com/3118571/lab-grown-meat-frankenburger-google/ (explaining that Mosa Meat is financially backed by Google co-founder Sergey Brin).

6 *See, e.g.*, Jesse Newman and Jacob Bunge, *The Transformation of the American Farm, in 18 Charts*, WASH. POST (Dec. 18, 2017), https://www.wsj.com/articles/the-transformation-of-the-american-farm-in-18-charts-1514474480.

7 *Major Gains in Efficiency of Livestock Systems Needed*, FOOD AND AGRIC. ORG. OF THE U.N. (Dec. 14, 2011), http://www.fao.org/news/story/en/item/116937/icode/.

8 *See Agriculture Technology*, NAT'L INST. OF FOOD AND AGRIC., U.S. DEPT. OF AGRIC., https://nifa.usda.gov/topic/agriculture-technology; Brandie Piper, *Technology in Agriculture: How Has Technology Changed Farming?*, MONSANTO (Apr. 24, 2017) https://monsanto.com/innovations/data-science/articles/technology-in-agriculture/.

9 RISK ASSESSMENT EVALUATION FOR CONCENTRATED ANIMAL FEEDING OPERATIONS, U.S. ENVTL. PROT. AGENCY (2004), at 7 ("In 1982, CAFOs comprised only 3% of all farm operations and more importantly, 35% of the total animal population. In 1997, CAFOs had risen to 5% of all farm operations and 50% of the animal population.")

10 *Census of Agriculture*, NAT'L AGRIC. STAT. SERV., U.S. DEPT. OF AGRIC. (2012).

A. Effect of Modern Meat Production on Environment

The rise in industrialized farming has consequences on the environment. In 2006, a study by the United Nations found that livestock production contributed eighteen percent of global greenhouse gas emissions – more than the entire transportation sector.[11] Within the United States, the Environmental Protection Agency (EPA) calculated that the agriculture sector is responsible for nearly eight percent of the nation's total greenhouse gas emissions.[12] The three main gases contributed by agricultural activities are carbon dioxide, methane, and nitrous oxide.[13] The EPA specifically noted, "Of all domestic animal types, beef and dairy cattle were by far the largest emitters of [methane]."[14] Between 1990 and 2015, carbon dioxide emissions increased by 24.8 percent, while methane emissions from agricultural activities increased by 12.3 percent.[15] Animal agriculture in the United States has a clear effect on the climate.

Additionally, animal agriculture affects water consumption. A 2012 study[16] of global meat production published in the scientific journal *Ecosystems* revealed that the water footprint[17] of beef is about four million gallons for one ton produced, while the water footprint of pig meat is roughly one and a half million gallons for one ton produced.[18] Whereas most vegetables have a water footprint of approximately eighty thousand gallons for one ton produced.[19] Within the United States, the U.S. Geological Survey calculated about two billion withdrawals of surface and ground water per day for livestock use.[20] The huge amount of water currently necessary to produce meat is concerning during a time when many geographic regions, such as California, experience more frequent and severe droughts.[21] Further distressing, if a

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[11] Henning Steinfeld et al., Livestock's Long Shadow: Environmental Issues and Options, FOOD AND AGRIC. ORG. OF THE U.N. (2006), http://www.fao.org/docrep/010/a0701e/a0701e00.htm. *Cf.* Robert Goodland & Jeff Anhang, *Livestock and Climate Change*, WORLD WATCH MAG., (2009), at 11 (claiming that livestock and their byproducts actually account for fifty-one percent of worldwide human-related greenhouse gas emissions annually).

[12] *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015*, U.S. ENVTL. PROT. AGENCY (2015), https://www.epa.gov/sites/production/files/2017-02/documents/2017_complete_report.pdf, at 5-1.

[13] *Id.*

[14] *Id.*

[15] *Id.* at 5-2.

[16] Mesfin M. Mekonnen and Arjen Y. Hoekstra, *A Global Assessment of the Water Footprint of Farm Animal Products*, ECOSYSTEMS 401–15 (2012).

[17] Water footprint is defined to include "the indirect water footprint of the feed and the direct water footprint related to the drinking water and service water consumed." *Id.* at 402.

[18] *Id.* at 405.

[19] *Id.* at 410.

[20] ESTIMATED USE OF WATER IN THE UNITED STATES IN 2010, U.S. GEO. SURV. at 29 (2010), https://pubs.usgs.gov/circ/1405/pdf/circ1405.pdf. Livestock water use was defined as "water associated with livestock watering, feedlots, dairy operations, and other on-farm needs. Livestock includes dairy cows and heifers, beef cattle and calves, sheep and lambs, goats, hogs and pigs, horses, and poultry." *Id.* at 28.

[21] *See, e.g.*, James McWilliams, *Meat Makes the Planet Thirsty*, N.Y. TIMES (Mar. 7, 2014), https://www.nytimes.com/2014/03/08/opinion/meat-makes-the-planet-thirsty.html.

company recalls meat due to lack of inspection or outbreak of infection, all of the water used to create the defective product is wasted.[22]

In addition to affecting the climate and water, animal agriculture also creates enormous waste and pollution. Instead of turning the animals to graze on nearby land and then using manure to fertilize the same land, modern animal feeding operations transport pre-made feed to the animals and then store the manure on-site.[23] The EPA wrote in a 2004 report that "[a]nimal farms produce as much manure as small and medium-size cities."[24] A dairy farm with 2,500 cows produces the waste load of a city with 411,000 people.[25] According to calculations on the COWspiracy website, livestock in the United States produce 116,000 pounds of waste per second.[26] The USDA admits, "Unmanaged manure contributes nutrients, disease-causing micro-organisms, and oxygen-demanding organics to the Nation's waters . . . Overapplication of animal manures to the land can degrade soil quality . . . Air quality can also be degraded."[27] This waste is usually stored on-site in liquid form, like a pond or lagoon next to the farm, or solid form, piled in a low-walled storage structure.[28]

Finally, when it comes to affecting the environment, animal agriculture impacts land use. About forty percent of the world's ice-free land is used to either grow livestock or grow food for the livestock.[29] A senior environmental writer for TIME Magazine wrote, "There may be no other single human activity that has a bigger impact on the planet than the raising of livestock."[30] A 2007 study by the USDA reported that, in the Unites States, "[l]ivestock grazing was the primary use of . . . 27 percent of all U.S. land and slightly more than half of all agricultural land. When cropland pasture [] and forested grazing land [] were added . . . total grazing land accounted for . . . 34 percent of the total U.S. land area and two-thirds of all agricultural land."[31] Overall, global and American meat production impacts the climate, water, pollution risk, and land use in a negative way.

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[22] *See id.* ("Further intensifying this ecological injustice are incidents such as the Rancho Feeding Corporation's recent recall of 8.7 million pounds of beef because the meat lacked a full federal inspection. That equals 631.6 million gallons of water wasted.")

[23] *Animal Manure Management*, U.S. DEPT. OF AGRIC. (Dec. 1995), https://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/technical/nra/rca/?cid=nrcs143_014211.

[24] RISK ASSESSMENT, *supra* note 9, at 7.

[25] *Id.*

[26] *The Facts*, COWspiracy, http://www.cowspiracy.com/facts/.

[27] *Animal Manure Management*, *supra* note 23.

[28] *Id.*

[29] Mario Herrero et al., *Biomass Use, Production, Feed Efficiencies, and Greenhouse Gas Emissions from Global Livestock Systems*, PROC. FOR THE NAT'L ACAD. OF SCI. (2013), http://www.pnas.org/content/pnas/early/2013/12/12/1308149110.full.pdf.

[30] Bryan Walsh, *The Triple Whopper Environmental Impact of Global Meat Production*, TIME MAG. (Dec. 16, 2013), http://science.time.com/2013/12/16/the-triple-whopper-environmental-impact-of-global-meat-production/.

[31] Cynthia Nickerson et al., *Major Uses of Land in the United States, 2007*, U.S. DEPT. OF AGRIC. (2007), https://www.ers.usda.gov/webdocs/publications/44625/11159_eib89_2_.pdf?v=41055.

B. Effect of Modern Meat Production on Economy

While meat production in the United States has an overall negative impact on the environment, the meat industry is quick to point out that it has an overall positive impact on the economy. Most information about economic impact is controlled by the North American Meat Institute (NAMI), a non-profit trade association headquartered in Washington D.C. For example, NAMI's website contains a page devoted exclusively to highlighting the importance of meat production for employment.[32] It lists statistics like, "[In 2013,] companies involved in meat production, along with their suppliers, distributors, retailers and ancillary industries employ 6.2 million people in the U.S. with jobs that total $200 billion in wages."[33] On an affiliated website called The Market Works, NAMI boasts how "[t]he U.S. meat and poultry supply is the most affordable in the world."[34] In a 2016 study commissioned by NAMI and posted on a website called Meat Fuels America, the statistics increased with a reported 5.4 million jobs provided by the meat and poultry industry accounting for 5.6 percent of gross domestic product.[35] Although one may be rightfully dubious about the precise statistics controlled by a lobbying group, there is little doubt that the meat industry does contribute substantially to the American economy.

C. Effect of Modern Meat Production on Human Health

As discussed, meat production has an overall negative impact on the environment and an overall positive impact on the economy. In terms of human health, meat has a rather neutral impact. Meat can be an excellent source of protein and other nutrients.[36] However, "most Americans eat more than 1.5 times the average daily protein requirement, and consume more than the recommended amount of foods from the USDA Protein Foods group."[37] Furthermore, certain types of meat, like red meat and processed meat (e.g., hot dogs, bacon, sausages) have been linked to increased risk of diseases, such as heart disease, type 2 diabetes, obesity, and earlier mortality.[38] This is because of high saturated fat and cholesterol content, and

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[32] *See The United States Meat Industry at a Glance*, N. AM. MEAT INST. (2017), https://www.meatinstitute.org/index.php?ht=d/sp/i/47465/pid/47465.

[33] *Id.*

[34] *The Meat and Poultry Industry: Basic Statistics*, THE MARKET WORKS (2018), http://www.themarketworks.org/stats.

[35] *Economic Impact*, MEAT FUELS AMERICA (2016), http://www.meatfuelsamerica.com.

[36] *See Science of Meat: Proteins*, EXPLORATORIUM, https://www.exploratorium.edu/cooking/meat/INT-proteins.html; Katie Hiscock, *Best Sources of Protein*, BBC GOOD FOOD (July 21, 2017), https://www.bbcgoodfood.com/howto/guide/best-sources-protein.

[37] *Health and Environmental Implications of U.S. Meat Consumption and Production*, CTR. FOR A LIVEABLE FUTURE, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH, https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/projects/meatless_monday/resources/meat_consumption.html. *See also U.S. Diets are Out of Balance with Federal Recommendations*, ECON. RES. SERV., U.S. DEPT. OF AGRIC. (Sept. 14, 2017), https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58334.

[38] *Health and Environmental Implications*, *supra* note 37. *See also* Harrison Wein, *Risk in Red Meat?*, NAT'L INST. OF HEALTH (Mar. 26, 2012), https://www.nih.gov/news-events/nih-research-matters/risk-red-meat.

carcinogenic compounds found in processed meat and formed during high-temperature cooking, along with other factors.[39]

In addition to the problems with the high-meat diet prevalent in the United States, the way in which meat is produced may also be a cause for health concern. The Johns Hopkins Bloomberg School of Public Health lists nine serious issues on its website as reasons for concern about modern meat production.[40] These reasons are: feed additives,[41] antibiotic resistance,[42] worker health,[43] animal welfare,[44] novel influenza,[45] animal waste,[46] rural communities,[47] health disparities,[48] and foodborne illness. In summary, meat is embedded in the American way of life, whether for good or for bad. While it would likely be futile to try to remove meat from American diets, there may be a healthier way of incorporating it.

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[39] *Health and Environmental Implications*, *supra* note 37.

[40] *See id.*

[41] *Id.* ("The feed given to industrially-raised [animals] . . . may contain antibiotics, arsenical drugs, rendered animal carcasses, and other ingredients that may lead to the introduction of harmful contaminants into our food supply.") *See also* Amy R. Sapkota et al., *What Do We Feed to Food-Production Animals? A Review of Animal Feed Ingredients and Their Potential Impacts on Human Health*, 115 ENVTL. HEALTH PERSP. 663–70 (2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1867957/.

[42] *Health and Environmental Implications*, *supra* note 37 ("The routine use of low doses of antibiotics in feed contributes to the development of antibiotic-resistant bacteria . . . [which] are more expensive and difficult to treat.") *See also* Rebecca R. Roberts et al., *Hospital and Societal Costs of Antimicrobial-Resistant Infections in a Chicago Teaching Hospital: Implications for Antibiotic Stewardship*, 49 CLINICAL INFECTIOUS DISEASES 1175–84 (2009), https://academic.oup.com/cid/article/49/8/1175/425330; Ellen K. Silbergeld et al., *Industrial Food Animal Production, Antimicrobial Resistance, and Human Health*, 29 ANN. REV. OF PUB. HEALTH 151–69 (2008), https://www.annualreviews.org/doi/10.1146/annurev.publhealth.29.020907.090904.

[43] *Health and Environmental Implications*, *supra* note 37 ("Workers in [industrial food animal production] operations may face numerous hazards, including toxic gases from animal waste, and crowded, unsanitary conditions ripe for the transmission of diseases from animals to workers, who might then spread infections to their communities.") *See also* Kelley J. Donham et al., *Community Health and Socioeconomic Issues Surrounding Concentrated Animal Feeding Operations*, 115 ENVTL. HEALTH PERSP. 317–20 (2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1817697/.

[44] *Health and Environmental Implications*, *supra* note 37 ("Practices [like overcrowding] that induce stress can increase animals' transmission of disease.") *See also* Marcos H. Rostagno, *Can Stress in Farm Animals Increase Food Safety Risk?*, 6 FOODBORNE PATHOGENS & DISEASE 767–76 (2009), https://www.liebertpub.com/doi/abs/10.1089/fpd.2009.0315.

[45] *Health and Environmental Implications*, *supra* note 37 ("Frequent contact among large populations of hogs, birds, and humans . . . offer ideal conditions for the generation of new influenza viruses.")

[46] *Id.* (explaining that runoff from waste piles has been linked to "the growth of toxic microorganisms in recreational waters" and exposure of downstream communities to groundwater contamination). *See also* Michael A. Mallin and Lawrence B. Cahoon, *Industrialized Animal Production: A Major Source of Nutrient and Microbial Pollution to Aquatic Ecosystems*, 24 POPULATION & ENV'T. 369-85 (2003).

[47] *Health and Environmental Implications*, *supra* note 37 ("People living near or downstream from [industrial food animal production] operations may be forced to cope with the health and social impacts of contaminated air and water. Odors from nearby operations are more than just unpleasant smells; they have been associated with high blood pressure, depression, anxiety, sleep disturbances, and other harms.")

[48] *Id.* ("In many cases, the burden of public health harms arising from [industrial food animal production] falls disproportionately upon low-income communities and communities of color.") *See also* Donham, *supra* note 43.

II. DEVELOPMENT OF LAB-GROWN MEAT

Theoretically, one way of making meat production better is to cut out the farm entirely. By growing meat in a laboratory, the negative environmental and public health consequences can be eliminated. This section describes the evolution, benefits, and drawbacks of the emergent lab-grown meat industry.

A. Funding the Frankenmeat of the Future

Who better to cultivate futuristic food than the National Aeronautics and Space Administration (NASA)? Picking up the idealistic goal first propounded by Dutch psychologist Willem van Eelen, NASA started experimenting with the idea of lab-grown meat as an alternative to pasty space food in the early 2000s.[49] A NASA-funded project by the NSR/Touro Applied BioScience Research Consortium created the first edible in vitro muscle protein from a goldfish.[50] Soon, forward-thinking investors and animal rights groups jumped on board.

In 2008 (later extended to 2014), People for the Ethical Treatment of Animals (PETA) announced a competition; PETA would award $1 million "to the first group that could create 'an in-vitro chicken-meat product that has a taste and texture indistinguishable from real chicken flesh.'"[51] PETA also funded a fellowship for a postdoctoral biological engineer to work with Vladimir Mironov, a well-known tissue researcher and associate professor in the Department of Cell Biology and Anatomy at the Medical University of South Carolina.[52] President and co-founder of PETA, Ingrid Newkirk, explained the group's motivation for backing this research, "If people are unwilling to stop eating animals by the billions, then what a joy to be able to give them animal flesh that comes without the horror of the slaughterhouse, the transport truck, and the mutilations, pain, and suffering of factory farming."[53]

In addition to animal rights activists like PETA, innovative entrepreneurs have demonstrated support for lab-grown meat as well. Sergey Brin, co-founder of Google, provided funding to Dutch company Mosa Meats for the first taste-test of a lab-grown burger, which occurred to the delight of hundreds of onlooking journalists in London in 2013.[54] The "cultured beef burger" was a five-ounce patty created from cow stem cells.[55] It cost just over $300,000 to produce.[56] Nutritional researcher Hanni Rützler and food writer Josh Schonwald were flown in to specially taste the creation.[57] Schonwald revealed that the burger tasted like a normal beef burger, albeit

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[49] *See* Michael Specter, *Test-Tube Burgers*, THE NEW YORKER (May 23, 2011), https://www.newyorker.com/magazine/2011/05/23/test-tube-burgers.

[50] *Id.*; *see also* MA Benjaminson et al., *In vitro edible muscle protein production system (MPPS): stage 1, fish*, 51 ACTA ASTRONAUT 879–89 (2002), https://www.ncbi.nlm.nih.gov/pubmed/12416526.

[51] Specter, *supra* note 49; *see also PETA's In Vitro Chicken Contest*, PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS, https://www.peta.org/features/vitro-meat-contest/.

[52] *Id.*

[53] *Id.*

[54] *See* Schonwald, *supra* note 5.

[55] *Id.*

[56] *Id.*

[57] *Our Story*, MOSA MEAT, http://mosameat.eu.

dry and slightly unnatural in color.[58] Mosa Meats showcased incredible potential, but the cost of utilizing the technology was almost prohibitive.

Within two years of the Mosa Meats taste-test, a similar company in the United States fried the first-ever lab-grown meatball at the lower cost of $18,000 per pound.[59] Memphis Meats, headquartered in San Francisco, seeks to "combin[e] the innovative spirit of Silicon Valley and the rich food traditions of the American south to provide a better meat and world."[60] Led by cardiologist Uma Valeti and stem cell biologist Nicholas Genovese,[61] Memphis Meats has been able to attract large donors and drive down the prohibitive cost initially incurred by Mosa Meats. In 2017, the company raised $17 million in fundraising from investors such as Bill Gates, Richard Branson, Suzy and Jack Welch, as well as leading agriculture company Cargill, Inc.[62] In 2018, Tyson Foods announced that it would also join the group of investors.[63] Tyson's press release explained, "We continue to invest significantly in our traditional meat business, but also believe in exploring additional opportunities for growth that give consumers more choices."[64] As the technology has become more established, innovators and even traditional agriculture corporations see the exciting potential "to provide sustainable protein options" in a world where demand for protein is expected to rise exponentially.[65]

B. The Science Behind the Meat

Various methods for growing meat in a laboratory have been proposed, such as the self-organizing technique, the scaffold-based technique, and the tissue engineering technique.[66] Through experimentation, the scaffold-based technique has emerged as realistic for large-scale production. This is the technique used by the

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[58] *See id.*; Schonwald, *supra* note 5.

[59] Marta Zaraska, *Lab-Grown Meat Is In Your Future, and It May Be Healthier Than the Real Stuff*, WASH. POST (May 2, 2016), https://www.washingtonpost.com/national/health-science/lab-grown-meat-is-in-your-future-and-it-may-be-healthier-than-the-real-stuff/2016/05/02/aa893f34-e630-11e5-a6f3-21ccdbc5f74e_story.html?utm_term=.0285050cc42e.

[60] *Our Story*, MEMPHIS MEATS, http://www.memphismeats.com/about-us/.

[61] *Meat the Team*, MEMPHIS MEATS, http://www.memphismeats.com/the-team/.

[62] *See* Christina Troitino, *Memphis Meats' Lab-Grown Meat Raises $17M With Help from Bill Gates and Richard Branson*, FORBES (Aug. 24, 2017), https://www.forbes.com/sites/christinatroitino/2017/08/24/memphis-meats-lab-grown-meat-raises-17m-with-help-from-bill-gates-and-richard-branson/#148fc41d3fd0; *Protein Innovation: Cargill Invests in Cultured Meats*, CARGILL (Aug. 23, 2017), https://www.cargill.com/story/protein-innovation-cargill-invests-in-cultured-meats ("Our strategic alliance with Memphis Meats is an exciting way for Cargill to explore the potential in growing the cultured meats segment of the protein market.")

[63] *See* Megan Durisin, *Tyson Joins Bill Gates, Cargill to Invest in Lab-Meat Producer*, BLOOMBERG (Jan. 29, 2018), https://www.bloomberg.com/news/articles/2018-01-29/tyson-joins-bill-gates-cargill-to-invest-in-lab-meat-producer.

[64] *Tyson Foods Invests in Cultured Meat with Stake in Memphis Meats*, TYSON FOODS (Jan. 29, 2018), https://www.tysonfoods.com/news/news-releases/2018/1/tyson-foods-invests-cultured-meat-stake-memphis-meats.

[65] *See Protein Innovation*, *supra* note 62.

[66] *See, e.g.*, Shruti Sharma et al., *In Vitro Meat Production System: Why and How?*, 52 JOURNAL OF FOOD SCI. & TECH. 7600–02 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4648904/

pioneering Dutch researcher William Van Eelen,[67] as well as Memphis Meats and Mosa Meat.[68]

First, a laboratory intending to grow meat must contain at least one (ideally many) bio-reactors.[69] A bio-reactor is a "high-tech vat that can provide the perfect conditions for growth."[70] Beer is produced using a similar method.[71] Instead of a "brewery," one researcher called a meat laboratory a "carnery."[72] The large, enclosed space of the bioreactor ensures that cells receive the right amount of fluids and movement.[73] Bio-reactors are expensive, but key to mass-production.

Once a bioreactor is installed, stem cells of an animal must be acquired. Stem cells are special because they can turn into the types of cells found in muscle.[74] The original stem cells can be taken from a small sample of live animal muscle.[75] There are three types of stem cells that have been identified as potentials for lab-grown meat: embryonic, satellite, and adult.[76] Satellite cells have generally been determined as the most suitable type of cell, as it is responsible for muscle regeneration after injury.[77] The cells reproduce and grow once immersed in a nutrient-rich serum.[78] Since stem cells can reproduce so quickly, theoretically, a few cells could produce tons of meat.[79]

Next, begins the proliferation phase. The goal of this phase is "to obtain the maximum number of cells from the starting batch of cells."[80] Using the scaffold-based technique, the growing cells are attached to a three-dimensional "scaffold."[81] An ideal scaffold is flexible and porous, allowing a nutrient-rich growth medium to seep into the cells as they continue to proliferate.[82] Muscle cells in a lab are just like

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67 Specter, *supra* note 49.

68 Mark J. Post, *Cultured Meat from Stem Cells: Challenges and Prospects*, 92 MEAT SCI. 297–301 (2012). Mark Post is the Chief Scientific Officer behind Mosa Meat. *Meet the Team*, MOSA MEAT, http://mosameat.eu.

69 *See id.* at 7602; Specter, *supra* note 49.

70 Tom Ireland, *The Artificial Meat Factory – The Science of Your Synthetic Supper*, BBC SCI. FOCUS (Aug. 25, 2017), http://www.sciencefocus.com/article/future/artificial-meat-factory.

71 Specter, *supra* note 49.

72 *Id.* ("Still, a 'carnery,' as Nicholas Genovese, the PETA-supported postdoctoral researcher [and Memphis Meats co-founder], has suggested such a factory be called, will need much more careful monitoring than a brewery.")

73 Sharma, *supra* note 66.

74 *See, e.g.*, Ireland, *supra* note 70.

75 Sharma, *supra* note 66, at 7601.

76 *Id.*

77 *See, e.g.*, *id.*; Post, *supra* note 68, at 299; *The Technology Behind Cultured Meat*, MOSA MEAT, http://mosameat.eu/technology.html.

78 Sharma, *supra* note 66, at 7601 ("What fundamentally supports and promotes the culturing of the cells is the culture medium, together with the appropriate growth factors as it provides the requisite nutrition for the growth of the tissue.")

79 Specter, *supra* note 49.

80 Post, *supra* note 68, at 299.

81 *See* Sharma, *supra* note 66, at 7602.

82 *Id.* The growth medium usually contains fetal bovine serum or mushroom extracts, but alternatives have been proposed. *Id.* at 7601–02; *see infra* II.C.2.

muscle cells on a human; they need to be exercised or they will atrophy.[83] The scaffold must be mechanized to stretch the growing muscle cells, to increase the size and protein content, as well as prevent deterioration.[84] Using a tissue engineering technique, the muscle precursor cells (called myoblasts) may be cultured together with other types of cells to "mimic the actual structure of muscle."[85] With this technique, electrical stimulation may exercise the cells.[86]

Eventually, the cells will be stretched and grown enough to "harvest." Keep in mind that the muscle will contain no bone, and there will be no unwanted animal parts. The resulting muscle tissue can either be packaged and sold or immediately cooked and consumed. A 2014 article estimated that "one bioreactor could make [] 56,400 pounds of meat a year . . . Assuming a person eats [] enough for 968 burgers [a year]—one bioreactor could feed 2,560 people."[87] Although scaffold-based stem cell meat may seem like a breakthrough alternative to traditional meat, there are some challenges to its commercial viability.

C. Benefits and Drawbacks of Lab-Grown Meat

The companies leading the charge of lab-grown meat tout many benefits. These include benefits to the environment, public health, and animal welfare. However, critics push back on these claims and also cite to economic concerns.

1. Benefits of Lab-Grown Meat

As mentioned above, modern meat production has a large and overall negative effect on the environment. Some of these negative effects would be significantly reduced, perhaps completely eliminated, if meat is grown in a laboratory. For example, beef and dairy cattle would no longer be emitting the same amount of methane. Agriculture would no longer occupy forty percent of the world's ice-free land, since lab-grown meat can be grown in city buildings.[88] Researchers from the University of Alberta explained:

It is suspected that [lab-grown meat] would have a reduced water, energy and land requirement because a) solely muscle tissue is cultivated, bypassing the development of by-products and non-skeletal muscle tissues; b) for the same mass of meat, tissue cultivation is anticipated to be faster than growth to a slaughter- ready age and c) in vitro meat production systems are capable of increasing in volume vertically, making deforestation to create pasture unnecessary.[89]

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[83] *Id.*

[84] *Id.*

[85] *Id.* at 7602.

[86] Post, *supra* note 68, at 300.

[87] Francie Diep, *What Does It Take to Make Meat from Stem Cells?*, POPULAR SCI. (May 21, 2014), https://www.popsci.com/article/science/what-does-it-take-make-meat-stem-cells.

[88] *See* Zachary Schneider, *In Vitro Meat: Space Travel, Cannibalism, and Federal Regulation*, 50 HOUS. L. REV. 991 (2013), at note 15 (citing I. Datar & M. Betti, *Possibilities for an In Vitro Meat Production System*, 11 INNOVATIVE FOOD SCI. & EMERGING TECH. 13, 19 (2010) (claiming that industrial scale in vitro meat production facilities would need to be three to five stories tall); Cliff Kuang, *Farming in the Sky*, POPULAR SCI. (Sept. 2008), at 41 (proposing vertical farms within cities)).

[89] Isha Datar & Mirko Betti, *Possibilities for an In Vitro Meat Production System*, 11 INNOVATIVE FOOD SCI. & EMERGING TECH. 14 (2009).

Because lab-grown meat could be grown and harvested at the same site, "countries which would normally rely on imported meats" with expensive and inefficient transportation costs could create their own markets.[90] The environmental benefits of laboratory-grown meat are very attractive to investors and consumers alike.

Similarly, the public health benefits of lab meat are appealing to consider. Since laboratories can be designed as sterile environments, the incidence of meat-based disease would decrease.[91] There would be no antibiotic use, because the meat would propagate under carefully controlled circumstances that do not require preventative treatment or induced growth.[92] In the future, each product could potentially be cultivated with modified vitamin and mineral content, making lab meat a healthier alternative to its traditional counterpart.[93]

Finally, vegans, vegetarians, and animal lovers may prefer laboratory meat for its animal welfare implications. As explained above, the method of farming meat in the United States has changed from idyllic family farms to industrial operations. Many believe the current practices to be inhumane for animals who are raised solely to breed and die. "Victimless" meat is a winning solution for those ethically concerned. Thus, PETA's early support of the concept. While these benefits are noteworthy, there are also drawbacks that have consistently challenged the industry.

2. Drawbacks of Lab-Grown Meat

The most obvious drawback of laboratory-made meat is the cost. Although the cost has been decreasing, with the first burger costing $300,000 in 2013 and the first pound of meatballs costing $18,000 in 2015, the expense is still prohibitive for general consumers. The man behind Memphis Meats, Uma Valeti, hopes to continue bringing down the cost by a thousand dollars per month.[94] "Our goal is to get to cost parity, and then beat commercial meat," he told Inc. Magazine in a 2017 interview.[95] While his goal is still distant, laboratory-made meat would generally have "high startup costs, but low operational costs," similar to an electric vehicle.[96] And with huge investments from the likes of Cargill and Bill Gates, the economic challenges may be overcome soon.

Another big drawback is the use of fetal bovine serum. For an industry that prides itself on having a positive effect for animal welfare, it is obviously hypocritical to extract blood from cow fetuses in slaughterhouses, remove the red blood cells, and

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[90] *Id.*

[91] *Id.* ("Myocyte culturing prevents the spread of animal-borne disease which may or may not affect meat products. Moreover, by reducing the amount of close quarter human-animal interaction, the incidence of epidemic zoonoses developing will decline.")

[92] *See id.* ("The employment of aseptic technique throughout the culturing process ensures that the meat product is free from contamination.")

[93] *See id.* ("Controlled conditions also offer the capacity for manipulation to create meat products with different nutritional, textural and taste profiles.")

[94] Jeff Bercovici, *Why This Cardiologist Is Betting That His Lab-Grown Meat Startup Can Solve the Global Food Crisis*, INC. (Oct. 24, 2017), https://www.inc.com/magazine/201711/jeff-bercovici/memphis-meats-lab-grown-meat-startup.html.

[95] *Id.*

[96] *Id.*

use the leftover material as a main ingredient in the stem cell nutrient serum.[97] Memphis Meats admits the use of fetal bovine serum to start its cell lines.[98] However, this hypocrisy is so glaring and problematic that alternatives are already being sought. Memphis Meats claimed that it would be replacing all fetal bovine serum with plant-based alternatives by the end of 2016.[99] In 2017, Memphis Meats changed its position to say, "We have validated a production method that does not require the use of any serum, and we are developing additional methods as we speak."[100] A new Dutch startup, Meatable, has been experimenting with a more finicky type of stem cell that comes from an animal's umbilical cord at birth, along with proprietary technology, to reach the same result of cell proliferation without the use of serum or death of an animal.[101] Although this shortcoming may take longer than planned to remedy, it has been recognized and addressed.

Some critics also push back on the idea that lab-grown meat is really better for the environment. In particular, lab-grown meat may require more energy. While animals perform a variety of functions to build muscle mass, including digestion of food, circulation of nutrients and oxygen, maintenance of an optimal body temperature, and protection against disease, laboratories will have to use fossil fuels to accomplish the same tasks.[102] One article gave the example of sterilization since, unlike animals, meat grown in a factory will not have an immune system, and therefore everything must be sterilized by hot water or chemicals "to avoid contamination with harmful microbes."[103] Additionally, inedible components such as feathers, hide, or blood will no longer be produced and synthetic materials may need to be created in another laboratory for use in pharmaceuticals, cosmetics, and other household or industrial purposes.[104] The counterargument is that engineers can optimize energy efficiency in a lab setting, since energy-intensive processes like sterilization will be identified beforehand.[105]

Of course, there is also the yuck factor that some people feel when confronted with the idea of eating meat grown in a petri dish.[106] Such "frankenfood" may seem unnatural, especially to people who grew up near or on farms. In 2013, the Pew Research Center conducted a poll of Americans on the future of technology.[107] Only

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[97] *See* Bercovici, *supra* note 94; Troitino, *supra* note 62.

[98] *See* Bercovici, *supra* note 94; Troitino, *supra* note 62.

[99] Troitino, *supra* note 62.

[100] Bercovici, *supra* note 94.

[101] *See* Erin Brodwin, *A New Lab-Grown Meat Startup May Have Overcome a Key Barrier to Making Meat Without Slaughter*, BUS. INSIDER (Sept. 28, 2018), https://www.businessinsider.com/lab-grown-meat-startup-solving-barrier-meat-without-slaughter-meatable-2018-9.

[102] Carolyn Mattick et al., *The Problem with Making Meat in a Factory*, SLATE (Sept. 28, 2015), http://www.slate.com/articles/technology/future_tense/2015/09/in_vitro_meat_probably_won_t_save_the_planet_yet.html.

[103] *Id.*

[104] *Id.*

[105] *Id.* This argument was made by Memphis Meats co-founder Nicholas Genovese.

[106] *See, e.g.*, Zaraska, *supra* note 59 ("For some people there's an ick factor to the idea of lab-grown meat.")

[107] Aaron Smith, *U.S. Views of Technology and the Future*, PEW RESEARCH CTR. (Apr. 17, 2014), http://www.pewinternet.org/2014/04/17/us-views-of-technology-and-the-future/.

one in five Americans (twenty percent) expressed a willingness to eat lab-grown meat.[108] Men were more likely than women (twenty-seven percent of men and fourteen percent of women say they would give lab-grown meat a try).[109] College graduates were about three times as likely as those who did not attend college (thirty percent versus eleven percent).[110] Another poll conducted by Michigan State University in March 2018 found similar results.[111] Clearly education may play a role in convincing consumers to try lab-grown meat. The feeling of disgust could also be overcome by accurately recreating the appearance, flavor, smell, and texture of traditional meat.[112] Despite each challenge, the laboratory meat market seems to be on the rise for the indefinite future, and laws should be adapted to accommodate accordingly.

III. ADAPTING THE LAW TO REGULATE LAB-GROWN MEAT

The next step before integrating lab-grown meat into the American diet is selecting federal laws to regulate its production and labeling. The choice must be made whether to broadly interpret current laws to apply to this new industry, or to create new laws altogether. Additional considerations include which agencies will play a role and how to even categorize lab-grown meat as a food. The following sections sketch out a suggested way to regulate lab-grown meat.

A. Relevant Federal Agencies

The United States federal government regulates food production by delegating authority to several different agencies: the Food and Drug Administration (FDA), the EPA, and the USDA. Each agency has different authority. Relevant for this paper, the Federal Food, Drug, and Cosmetic Act (FDCA) gives FDA authority over the quality of foods including additives.[113] The FDCA defines "food" as "articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article."[114] The FDCA defines "food additives" as "any substance [that may] becom[e] a component or otherwise affect[] the characteristics of any food."[115] These food additive substances may need special approval for safety,

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[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] *Food Literacy and Engagement Poll*, MI. STATE UNIV. (Mar. 26, 2018), https://www.canr.msu.edu/news/msu-food-literacy-and-engagement-poll-wave-ii. *See also* Walter Johnson, Andrew Maynard, Sheril Kershenbaum, *Burgers Grown in a Lab are Heading to Your Plate. Will You Bite?*, WASH. POST (Sept. 9, 2018), https://www.washingtonpost.com/national/health-science/burgers-grown-in-a-lab-are-heading-to-your-plate-will-you-bite/2018/09/07/1d048720-b060-11e8-a20b-5f4f84429666_story.html?utm_term=.0e04457f7f2f (explaining that households earning $75,000 or more per year, eighteen-to-twenty-nine-year-olds, college graduates, and women were categories statistically more likely to try artificially produced meat).

[112] *See* Post, *supra* note 68.

[113] *What Does FDA Regulate?*, FDA, https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm (Last updated: August 22, 2018).

[114] 21 U.S.C. § 321(f) (2016).

[115] 21 U.S.C. § 321(s) (2016).

or may be considered "generally recognized as safe" (GRAS).[116] With respect to genetically modified organisms (GMOs), FDA released a policy statement saying that any GMO product "that differs significantly in structure, function, or composition from substances found currently in food," must be pre-approved as a food additive before entering the market.[117] However, the FFDCA contains a specific exemption for "meats and meat food products," which are instead regulated by the USDA.[118] In other words, FDA has authority over "food additives" and GMOs, but not over meat.[119]

The EPA "sets limits on how much of a pesticide may be used on food during growing and processing, and how much can remain on the food you buy."[120] The EPA also implements and enforces the Clean Water Act and Clean Air Act, which may impact food processing facilities.[121] Therefore, the EPA is usually involved with both genetically engineered foods and traditional meat facilities.

The USDA's Food Safety and Inspection Service (FSIS) "is the public health agency . . . responsible for ensuring that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."[122] The FSIS derives its authority from the Federal Meat Inspection Act of 1906 (FMIA), the Poultry Products Inspection Act of 1957, and the Egg Products Inspection Act of 1970.[123] The FMIA describes the requirements for sanitary slaughtering, inspections of products and facilities, and labeling. Under the FMIA, "meat" is not defined, but "meat food product" means "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."[124] While these are the three main agencies generally in charge of food standards in the United States, not all three are necessarily involved with every food product.

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[116] *Id.*

[117] FDA, *Statement of Policy: Foods Derived from New Plant Varieties*, 57 Fed. Reg. 22,984 (May 29, 1992), available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/ Biotechnology/ucm096095.htm.

[118] 21 U.S.C. § 392 (2009).

[119] That being said, FDA does regulate some aspects of meat, such as the feed eaten by animals intended for slaughter and the casings of sausages. Gretchen Goetz, *Who Inspects What? A Food Safety Scramble*, FOOD SAFETY NEWS (Dec. 16, 2010), http://www.foodsafetynews.com/2010/12/who-inspects-what-a-food-safety-scramble/#.WuTXji-ZPVo.

[120] *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ AboutFDA/Transparency/Basics/ucm194879.htm (Last updated: August 22, 2018).

[121] *Laws*, U.S. ENVTL. PROT. AGENCY, https://www.epa.gov/laws-regulations.

[122] *Summary of Federal Inspection Requirements for Meat Products*, U.S. DEP'T OF AGRIC., https://www.fsis.usda.gov/wps/wcm/connect/e6658a9c-915f-4283-beaf-a827b35e906a/Fed-Food-Inspect-Requirements.pdf?MOD=AJPERES (Last updated: Sept. 2015).

[123] *FSIS Statutes, Mission, and Authority*, U.S. DEP'T OF AGRIC., https://www.fsis.usda.gov/wps/wcm/connect/c0c8145f-927f-4a36-8c3e-b815adb24811/2_IM_ Statutes.pdf?MOD=AJPERES (Last updated: March 2015).

[124] 21 U.S.C. § 601(j). This definition explicitly excludes "products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe." *Id.*

B. Which Agency Should Regulate Lab-Grown Meat Production & How?

Eventually, as the industry expands and the technology progresses, a federal rulemaking may occur and potentially new laws or regulations written to directly address the subject. Both sides of the market, Memphis Meats and the North American Meat Institute, have requested the Administration to "clarify the regulatory framework" for "cell-based meat and poultry."[125] As the industry is just getting off the ground, lab-grown meat should be considered a "meat," falling under the purview of the USDA through its Federal Meat Inspection Act authority.

Lab-grown meat is appropriately regulated by the USDA FSIS because it falls within the FMIA definition of "meat food product." It is a "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."[126] This interpretation was supported by the National Cattlemen's Beef Association (NCBA), who wrote in a letter dated April 10, 2018 to the Acting Deputy Under Secretary for Food Safety:

USDA should assert jurisdiction over foods consisting of, isolated from or produced from cell culture or tissue culture derived from livestock and poultry animals or their parts. While cell cultured, or lab-grown meat products are certainly new, they are nonetheless derived from parts of a carcass, in this case stem cells, and therefore fall within the statutory definition of a meat food products.[127]

The NCBA's letter was written in response to a Petition for Rulemaking on labeling (discussed *infra* Part III.C), and its position is clearly a political strategy.[128] However, the legal interpretation is correct, based on the plain meaning of the law and the scientific process by which lab-grown meat is created. Furthermore, NCBA is correct that "FSIS has developed unparalleled expertise and . . . FSIS jurisdiction is the only way to ensure consumers are protected from perishable meat food products, and is applicable regardless of the . . . production method."[129] Being regulated by the USDA means that laboratories would need to comply with inspection requirements under 21 U.S.C. § 606(a), storage requirements under 21 U.S.C. § 624, sanitation requirements under 21 U.S.C. § 608, as well as regulatory requirements under 9 C.F.R. Chapter III, Subchapter E.

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[125] *See* Letter from Uma Valeti, Co-Founder and CEO, Memphis Meats, and Barry Carpenter, President and CEO, North American Meat Institute, to President Donald Trump (Aug. 23, 2018), https://www.drovers.com/sites/default/files/inline-files/MM%20-%20NAMI%20White%20House%20Letter%208.23.182.pdf. This joint letter recommends that the "FDA should have oversight over pre-market safety evaluations" while the "USDA should regulate cell-based meat and poultry products." *Id.* at 2.

[126] *Id.*

[127] Letter from Kevin Kester, President, National Cattlemen's Beef Association, to Carmen M. Rottenberg, Acting Deputy Under Secretary for Food Safety, U.S. DEP'T OF AGRIC. (Apr. 10, 2018), https://www.fsis.usda.gov/wps/wcm/connect/6372c970-c9c0-421f-aaa6-e25255663cee/18-01-NCBA-Comments-Opposition-Petition-041018.pdf?MOD=AJPERES.

[128] *See* Leanna Garfield, *The Battle Between the Beef Industry and Silicon Valley's Lab-Grown Meat Startups Is Heating Up*, BUS. INSIDER (Apr. 16, 2018), http://www.businessinsider.com/beef-companies-file-petition-against-lab-grown-meat-startups-2018-2 ("Initially, the NCBA's position may seem counterintuitive. But . . . the move is likely part of a larger strategy to fight cultured meat startups. By putting their products under the oversight of the USDA, lab-grown meat companies would need to adhere to USDA's existing regulations on meat, which could hamper research and development.").

[129] Letter from Kevin Kester, *supra* note 127, at 2.

The USDA FSIS should also draft new regulatory language[130] to clarify that an animal need not be slaughtered to fall under FSIS jurisdiction, so long as the product is grown from the cell of an animal that is otherwise governed by meat safety laws, like a cow, pig, or goat. This clarification could be achieved most smoothly by adding one general regulation to 9 C.F.R. Chapter III. Alternatively, the USDA FSIS could write more specific regulatory language to address each relevant statute. For example, a new regulation addressing 21 U.S.C. § 608 that explains "all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which amenable species are slaughtered and the meat and meat food products thereof are prepared for commerce" *includes* laboratories growing cultured meat, rather than just facilities where animals are "*slaughtered and*" meat food products are prepared. In sum, the production of lab-grown meat can be regulated by the USDA FSIS with few adjustments to the current regulatory regime.

Some wrongly argue that lab-grown meat should instead be regulated as a food additive or genetically engineered product by FDA under the FDCA. This argument reasons that FDA regulates cloned foods and GMOs, and "cloning and genetic engineering techniques bear similarities to certain in vitro meat production techniques."[131] However, this reasoning is not correct based on the science. Lab-grown meat should not be treated by FDA as a "food additive" because it does not "differ significantly in structure, function, or composition from substances currently found in food." If grown properly, the product will have the same structure and composition as traditional meat, since it is made directly from animal cells.[132] There is no cloning involved, as the cells are regenerating naturally.

Nor should lab-grown meat be treated as a GMO. Genetic engineering involves the incorporation of "new genes from one species into a completely unrelated species . . . [thereby] optimizing agricultural performance or facilitating the production of valuable [] substances."[133] The laboratory meat companies themselves are adamantly opposed to this categorization. Mosa Meat's website specifically says, "For the record: cultured meat is fundamentally different from genetically modified food. No genetic modification is involved in this process. Tissue cultured meat is normal meat; it is made from normal muscle cells."[134] The standard techniques used for genetic engineering, such as insertion, deletion, activation, or mutation of a gene,

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[130]New regulatory language would need to be approved through a Notice and Comment Rulemaking process, required by the Administrative Procedure Act, 5 U.S.C. § 553.

[131]*See, e.g.*, Schneider, *supra* note 88, at 1014.

[132]This paper is not addressing the possibility that lab-grown meat may someday be manipulated to contain certain nutrients, since that is not a currently-used method of production. The only substances that may need to be regulated as "food additives" by FDA are the scaffolding, if an edible scaffold is used, and the nutrient serum in which the meat is grown. As new and previously untested additives, these may need to undergo extra review to determine their safety, pursuant to 21 U.S.C. § 348. If the nutrient serum is created from mushroom extract, as has been proposed, it is likely that the serum would be considered "generally recognized as safe." Presently, it is unclear if either substance would truly be "added" to the final product, and neither would change the fact that the meat itself contains only animal cells.

[133]Theresa Phillips, *Genetically Modified Organisms (GMOs): Transgenic Crops and Recombinant DNA Technology*, 1 NATURE EDUC. 213 (2008), https://www.nature.com/scitable/topicpage/genetically-modified-organisms-gmos-transgenic-crops-and-732.

[134]*The Technology Behind Cultured Meat*, MOSA MEAT, https://mosameat.eu/technology.html.

are not required to produce cultured meat. Furthermore, cultured meat is composed of a tissue, not an entire organism. Accordingly, it is not a GMO.[135]

It is worth noting that no laboratory currently uses pesticides on their cultured meat, so the EPA may not be involved with lab-grown meat production at all. Potentially, the EPA could be involved to the extent of permitting water use or waste by the laboratories under the Clean Water Act.[136] Additionally, the EPA may regulate air emissions from laboratories under the Clean Air Act. But the EPA's involvement would likely be limited to regulating details about the facility, not the lab-grown meat itself. Therefore, the main federal agency regulating lab-grown meat should be the USDA.

C. How to Regulate Lab-Grown Meat Labeling?

In addition to complying with inspection, sanitation, and storage requirements, lab-grown meat would also need to comply with labeling requirements under the FMIA and USDA-promulgated regulations. This means that after the meat food product has been inspected and approved, the container must include a label which says the contents have been "inspected and passed."[137] The label will be considered "misbranded" if it is "false or misleading in any particular," "offered for sale under the name of another food," or "an imitation of another food" and the label does not clearly state the word "imitation" in a "type of uniform size and prominence."[138]

In February 2018, the U.S. Cattlemen's Association (USCA) filed a Petition for Rulemaking to the USDA arguing that lab-grown meat should not be labeled as "meat."[139] The fifteen-page Petition asks the USDA to strictly limit application of the words "meat" and "beef" to products from animals that have been "born, raised, and slaughtered in the traditional manner."[140] It takes direct aim at both "synthetic beef products" which are "derived from plants, insects and other non-animal components" such as the Impossible Burger, as well as "lab grown product from animal cells."[141] These "alternative products" may cause "consumer confusion in the market place,"[142] USCA claims, if allowed to use the words "meat" or "beef" anywhere in the label, because they are imitations and do not say that word clearly, as required by

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[135]Rather than compare to a GMO, some have aptly commented that cultured meat more closely resembles hydroponic vegetables, which are grown without soil in a nutrient-rich solvent. *See* Lakshmi Sandhana, *Test Tube Meat Nears Dinner Table*, WIRED (June 21, 2006), https://web.archive.org/web/20130819005637/http://www.wired.com/science/discoveries/news/2006/06/71201. *See also Hydroponic Systems 101*, FULL BLOOM HYDROPONICS, http://www.fullbloomhydroponics.net/hydroponic-systems-101/ (defining "hydroponic").

[136]An interesting question for another paper would be whether lab-grown meat waste water qualifies as agricultural non-point source pollution under the Clean Water Act. Concentrated animal feeding operations (CAFOs) are defined as "point sources" and therefore subject to the Clean Water Act. 33 U.S.C. § 1362(14). However, agricultural stormwater discharges and return flows from irrigated agriculture are non-point sources, and not regulated. *Id.*

[137]21 U.S.C. § 607(a).

[138]21 U.S.C. § 601(n)(1)–(3).

[139]U.S. Cattlemen's Association, Petition for the Imposition of Beef and Meat Labeling Requirements to the U.S. Department of Agriculture Food Safety and Inspection Service 1 (Feb. 9, 2018).

[140]*Id.* at 2.

[141]*Id.* at 9, 10.

[142]*Id.* at 4.

law.[143] By providing common dictionary and statutory definitions of the disputed words, the USCA argues that "meat" means slaughter, or the product is misbranded under the FMIA.[144] Ultimately, the USCA wants lab-grown meat to be excluded from the FFDCA "meat" exemption and therefore fall under FDA, rather than USDA, jurisdiction.

The USCA Petition brings up valid points about the importance of carefully labeling meat products. However, its arguments are off-base for lab-grown meat, and the National Cattlemen's Beef Association agrees.[145] In its response letter, the NCBA states its belief "that the petitioners have conflated issues related to marketing lab-grown meat derived from cell or tissue culture with other synthetic products derived from plants, insects or other non-animal sources being marketed as meat."[146] For the reasons mentioned in Part III.B., the NCBA accurately understands the science behind lab-grown meat and the reasons that it makes sense legally and logistically for the term "meat" and USDA jurisdiction to apply. Furthermore, the USCA's policy argument that lab-grown meat should be relabeled so as not to cause confusion when it "directly compete[s]" against traditional beef products is misguided. As one journalist pointed out, the target demographic for lab-grown meat is "likely to embrace these new products . . . because they don't want conventional meat products."[147] If an alternative label or "imitation" brand is used, "it's very possible that . . . would hype, not hinder, sales."[148] In conclusion, the legal and policy arguments made by the USCA to categorize and label lab-grown meat as an imitation under FDA's jurisdiction do not make sense, given the reality of how lab meat is grown. Instead, lab meat should be regulated by the USDA FSIS pursuant to its FMIA authority.

CONCLUSION

Lab-grown meat is a burgeoning industry that has the potential to ameliorate the negative environmental, public health, and animal welfare consequences of traditional meat production in the United States and globally. While lab meat has yet to hit grocery store shelves, the American legal system should anticipate its imminent arrival. After all, lab-grown meat is "an 'and,' not an 'or,' solution, and the latest in a long history of innovation in American agriculture."[149] This paper advocated for the USDA to regulate production and labeling of lab-grown meat using its current statutory authority under the Federal Meat Inspection Act (FMIA).

On November 16, 2018, FDA and USDA released a press statement announcing that the two agencies had agreed to "jointly oversee the production of cell-cultured food products derived from livestock and poultry," with FDA overseeing "cell

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[143] *Id.* at 5.

[144] *Id.* at 5, 6.

[145] For a short discussion of why similar industry groups are disagreeing on this issue, see Garfield, *supra* note 128.

[146] Letter from Kevin Kester, *supra* note 127.

[147] Dan Murphy, *Setting a Trap for Alt-Meat?*, DROVERS (Apr. 16, 2018), https://www.drovers.com/article/murphy-setting-trap-alt-meat.

[148] *Id.*

[149] Letter from Uma Valeti and Barry Carpenter, *supra* note 125.

collection, cell banks, and cell growth and differentiation" and the USDA overseeing "the production and labeling of food products derived from the cells of livestock and poultry."[150] The details of this framework have yet to be worked out and, as this paper explained, the agencies may need to write regulatory language to clarify that lab-grown meat is new, but it is still "meat" under the law. Then, it will be up to consumers to determine the industry's success. Will consumers get over the yuck factor? "There's nothing natural about a chicken that's given growth promoters and raised in a shed with 10,000 others," a graduate student who worked on the original laboratory-meat goldfish experiment says.[151] "As consumers become educated, a product like this would gain appeal."[152]

[150]Press Release, Sonny Perdue and Scott Gottlieb, USDA Secretary and FDA Commissioner, On the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry (Nov. 16, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626117.htm.

[151]Specter, *supra* note 49.

[152]*Id.*