

“Cultured Meat”: Lab-Grown Beef and Regulating the Future Meat Market

Jennifer Penn

ABSTRACT

Livestock production accounts for 19 percent of greenhouse gas (GHG) emissions and 9 percent of anthropogenic GHG emissions. It requires up to 30 percent of all land surface area on earth, 33 percent of all arable land, and 70 percent of agricultural land. It contributes to climate change in a myriad of ways, including land erosion, water contamination, and abundant resource use. Current practices are not sustainable for a rapidly growing population. Lab-grown meat, also known as cultured meat, provides an alternative that may address many of the environmental harms stemming from livestock production. Cultured meat requires 99 percent less land, 90 percent less water, and 45 percent less energy, which would help accommodate population growth while lowering food-based ecological impacts, including climate change. It can also be placed in areas inhospitable to traditional livestock production, and it would reduce animal cruelty. Currently, however, the federal statutory and regulatory framework governing livestock production is not prepared to address cultured meat. After introducing cultured meat and the technology behind it, this essay explores how current federal regulations fail to adequately address this development. The essay concludes by recommending

the adoption of new regulations to clarify the growth, inspection, certification, and sale of cultured meat in the United States.

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INTRODUCTION

Consumers in the United States eat around fifty-two billion pounds of meat per year, averaging just over 270 pounds per person.¹ It has been documented that one pound of hamburger requires 26.8 pounds of feed, 232 square meters of farmland, and 4,144 British Thermal Units (BTUs) of energy.² Imagine if consumers were able to buy ground beef that had been produced in a laboratory and made far fewer demands on natural resources. Cultured meat is the process of taking a single cell of muscle tissue from a cow and replicating it in a controlled setting to create layers of muscle that can be ground together to

1 Eliza Barclay, *A Nation of Meat Eaters: See How It All Adds Up*, NAT’L PUBLIC RADIO: THE SALT (June 27, 2012, 3:03 AM), <http://www.npr.org/sections/thesalt/2012/06/27/155527365/visualizing-a-nation-of-meat-eaters> [<https://perma.cc/H9SM-E638>].

2 *Id.*

produce ground beef. This laboratory process to create one pound of cultured meat requires no feed, 43.6 gallons of water, less than 1 square foot of farmland, and up to 45 percent less energy.³ If cultured meat were substituted for ground meat, consumers could save 26.8 pounds of feed, which could be repurposed to feed the growing population or create ethanol. This would also free up 167.6 gallons of water for use in other sectors, perhaps creating alternative solutions for crises like the recent one occurring in Flint, Michigan. Additionally, 3,455 square feet could be reforested or reclaimed for natural landscape and carbon sinks. Available land, or it could be dedicated to producing food for the world's expanding population. The use of fossil fuel energy could be cut almost in half. A laboratory running on renewable energy could entirely eliminate its dependence on fossil fuels.

While this scenario seems like science fiction for most, it is the fervent hope of those striving to make cultured meat a reality. Cultured meat is not the single answer to the challenges facing our climate, as there are many other causes and impacts that need to be addressed. That being said, traditional livestock practices have significantly contributed to climate change, which has, in turn, begun to impact traditional livestock practices. A drastic change needs to be made to keep the system from becoming a positive feedback loop. One in which climate change means more problems raising livestock, thus causing livestock farmers to produce more animals, which releases more Greenhouse Gases (GHGs) and increases climate change effects in severity.

A few decades ago, meat produced through cloning animals seemed improbable. Now meat harvested from the offspring of cloned animals is already on the shelves. Although cultured meat may face similarly intense challenges, it can overcome those barriers and solve many of the problems livestock farming faces today.

3 M. Joost Teixeira de Mattos & Hannah L. Tuomisto, *Environmental Impacts of Cultured Meat Production*, 45 ENV'TL SCI. & TECH. 6117, 6117 (June 15, 2011) (converted from metric to imperial).

To determine the feasibility of exchanging meat, such as ground beef, for cultured meat, Part I defines and explains the product. Part II explores why consumers would be interested in cultured meat over traditional meat, such as the environmental and humanitarian concerns inherent in attempting to produce enough animal protein to feed the world’s growing population. Part III examines the legal framework for inspection, certification, and sale of cultured meat. Cultured meat could be adopted into the Federal Drug Administration (FDA) meat product provisions, the FDA genetically modified organism provisions, or the United States Department of Agriculture (USDA) meat provisions. The Conclusion suggests an alternative—that cultured meat may need to its own provisions within the legal framework. If it is adequately regulated, cultured meat could soon provide an alternative to traditionally-produced meat.

I. WHAT IS CULTURED MEAT?

Cultured meat is one of the newest additions to a field called cellular agriculture.⁴ Cellular agriculture is the process of taking cells from animals, placing those cells into a controlled environment, and growing those cells.⁵ The insulin used by most diabetics today is made using this process:⁶ human insulin cells from humans are injected into yeast and grown in a lab. Scientists are able to grow insulin that is genetically identical to human insulin.⁷ By switching from harvesting bovine insulin to creating human insulin in a laboratory, scientists made the process safer and the supply more consistent.⁸ Scientists are also using this technology to grow living, transplantable tissue for

⁴ *About, NEW HARVEST*, <http://www.new-harvest.org/about> [<https://perma.cc/ZH7G-V8SX>].

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

medical use.⁹

Growing a fully functional organ, such as skin, is a difficult and rigorous process. The tissue must survive transportation and transplantation to become a working part of the body.¹⁰ Cultured meat, by contrast, is much less demanding because it only needs to meet certain nutritional, textural, and taste parameters. It does not need to meet any functional parameters.¹¹

Although this process can be applied to any animal muscle, this paper specifically compares traditionally produced beef with bovine cultured meat. To create a cultured hamburger, stem cells are extracted from bovine muscle tissue.¹² Those cells are then placed in a petri dish for the first cycle of growth, where they grow, divide, and replicate on their own.¹³ The result is a myotube of muscle cells that is then placed around a cylinder of gelatin with other myotubes.¹⁴ This donut-shaped ring of muscle cells attaches to the gelatin and then “exercises”; it expands, and contracts on its own, causing the muscle to grow and produce muscle tissue just as it would if it were part of a cow’s shoulder muscle.¹⁵ After time, these muscle cells grow into a layer of tissue the width of the petri dish and approximately one-half a millimeter in height.¹⁶

This single layer of bovine muscle tissue is then combined with other layers (as many as twenty thousand) and ground into

9 *Id.*

10 *Id.*

11 *Id.*

12 Cultured Beef, *Burger tasting London Aug 2013*, YouTube (Aug. 7, 2013), https://www.youtube.com/watch?v=_Cy2x2QR968 [hereinafter *Burger Tasting* video]; Cultured Beef, *Cultured Beef Process*, YouTube (Aug. 6, 2013), <https://www.youtube.com/watch?v=3LKsSEbSrUQ> [hereinafter *Cultured Beef Process* video]; *Mark Post’s Cultured Beef*, NEW HARVEST, http://www.new-harvest.org/mark_post_cultured_beef [<https://perma.cc/5DZK-7ZK2>].

13 *Cultured Beef Process* video, *supra* note 12; *Mark Post’s Cultured Beef*, *supra* note 12.

14 *Cultured Beef Process* video, *supra* note 12.

15 *Id.*

16 *Mark Post’s Cultured Beef*, *supra* note 12.

hamburger for easier cooking.¹⁷ The resulting product is then mixed with a limited amount of egg powder and breadcrumbs to create a hamburger patty that looks and cooks like a traditional hamburger patty.¹⁸ According to a study conducted of a test burger in August 2013, it also has the same texture, but with a taste between a traditional beef patty and a leading vegetarian substitute.¹⁹ This textural similarity but slightly lighter taste could be due to the lack of fat and iron from blood flow found in traditional meat.²⁰ Since this study, labs have begun to produce the other components necessary to bring the taste closer to that of a traditional hamburger.

II. WHY CHOOSE CULTURED MEAT?

[Livestock production] accounts for 40 percent of agricultural gross domestic product (GDP). It employs 1.3 billion people and creates livelihoods for one billion of the world’s poor. Livestock products provide one-third of humanity’s protein intake, and are a contributing cause of obesity and a potential remedy for undernourishment.²¹

A. Environmental Concerns

Climate change is the most serious problem facing the world today. GHG increases cause such effects as rising global temperatures, melting polar ice-caps and permafrost, rising sea levels, increasing extreme weather patterns, and natural disasters, ranging from toxic smog days to tsunamis that destroy

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Burger Tasting* video, *supra* note 12.

²⁰ *Burger Tasting* video, *supra* note 12.

²¹ HENNING STEINFELD ET AL., FOOD & AGRIC. ORG. OF THE U.N., LIVESTOCK ENV’T & DEV. INITIATIVE, LIVESTOCK’S LONG SHADOW: ENVIRONMENTAL ISSUES AND OPTIONS at xx (2016), <ftp://ftp.fao.org/docrep/fao/010/a0701e/a0701e.pdf> [<https://perma.cc/H38W-4SKN>].

entire islands.²² This paper accepts the realities of climate change and delves solely into the contributions of livestock. Although people traditionally associate transportation and energy production with GHG emissions, livestock production contributes more than both the transportation and the energy production sectors, accounting for 18 percent of all GHG emissions.²³ Livestock production is responsible for some of the most potent and heat-trapping GHGs, including 37 percent of anthropogenic emissions of methane, 65 percent of anthropogenic nitrous oxide emissions, and 64 percent of anthropogenic ammonia emissions.²⁴ Even if all livestock farmers and processors switched to best available practices, however, GHG emissions would still be far too high to have an effect on climate change.

GHG emissions are not the only problem. Livestock production is the largest anthropogenic (human-made) use of land.²⁵ When including land used to feed raise livestock, 30 percent of the earth's land is devoted to livestock production.²⁶ Land used for livestock production is highly susceptible to over-grazing, compaction, erosion, and run-off pollution.²⁷ Livestock production accounts for the vast majority of deforested land and for 70 percent of all agricultural land, and it is responsible for over 8 percent of global human water use.²⁸ It produces animal waste and antibiotic/hormone runoff from the farms in addition to the chemicals from the tanneries and those added to soils for feed crops.²⁹ It is also a significant contributor to water pollution, with effects including: "eutrophication, 'dead' zones in coastal areas, degradation of coral reefs, human health challenges, [and] emergence of antibiotic resistance."³⁰

²² *Id.* at xxi.

²³ *Id.* (measured in CO2 equivalent).

²⁴ *Id.* at xxi, 272.

²⁵ *Id.* at xxi.

²⁶ *Id.*

²⁷ *Id.* at 145, 185, 193.

²⁸ *Id.* at xxi–xxii.

²⁹ *Id.* at xxii.

³⁰ *Id.* at xxii.

Within the United States, livestock production causes 55 percent of erosion, 37 percent of pesticide use, 50 percent of antibiotic use, and 33 percent of nitrogen and phosphorus water pollution.³¹ Additionally, “by compacting soil, reducing infiltration, degrading the banks of watercourses, drying up floodplains and lowering water tables,” livestock impact freshwater replenishment.³² Meanwhile, runoff increases and dry season flows reduce because of livestock’s impact on deforestation.³³

While traditional practices may not have adequate solutions for issues of climate change, cultured meat may provide an alternative. “Cultured meat is sustainable, creates far fewer greenhouse gases than conventional meat, is safer, and doesn’t harm animals.”³⁴ One calorie of beef requires twenty-three calories of feed, while one calorie of cultured meat requires only three calories of input.³⁵ This 87 percent decrease in the amount of energy needed to create one calorie of meat would also substantially decrease the associated GHG emissions. Similarly, cultured meat can reduce 99 percent of the land and 90 percent of the water that is currently devoted to steak, sausage, and bacon production alone.³⁶ This ability to reduce the consumption of land, water, and energy use while also mitigating GHG emissions makes cultured meat an intriguing option to solve the challenges of traditional livestock production.

31 *Id.* at 167.

32 *Id.* at xxii.

33 *Id.*

34 Press Release, Memphis Meats, New Memphis Meats Campaign Activates Supporters (Feb. 1, 2016), <http://www.memphismeats.com/press-releases> [<https://perma.cc/ZV77-5ZCG>] [hereinafter Memphis Meats Press Release] (quoting Bruce Friedrich, Executive Director of The Good Food Institute).

35 *Id.*

36 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-a6f3-21ccd5f74e_story.html [<https://perma.cc/8Z7N-ZZFV>].

B. Humanitarian Concerns

There are some ethical concerns inherent in the artificial growth of a form of living tissue. Cloned animals and lab-grown human insulin are discussed elsewhere in this paper, but the broader ethical issues of lab-grown muscle are best left to another paper. And although there are concerns regarding animal cruelty and abuses in factory farm operations, this paper focuses on the challenges of food security and availability.

A major humanitarian concern is food security and the question of how to make protein available for the world's growing population. This problem is so pervasive that it is even written into U.S. foreign policy.

It is the policy of the United States to use its abundant agricultural productivity to promote the foreign policy of the United States by enhancing the food security of the developing world through the use of agricultural commodities and local currencies accruing under this chapter to—

- combat world hunger and malnutrition and their causes;
- promote broad-based, equitable, and sustainable development, including agricultural development;
- expand international trade;
- foster and encourage the development of private enterprise and democratic participation in developing countries; and
- prevent conflicts.³⁷

Across the world, the number of people with access to the recommended amount of protein is miniscule and diminishing. In the United States alone, the average protein supply per day has dropped from 162 grams in 2006 to 2008 to 160 grams in 2009 to 2011.³⁸ The average supply of animal protein over those

³⁷ Food for Peace, 7 U.S.C. § 1691 (2012).

³⁸ *FAO Stats by Country Indicator*, Food & Agric. Org. of the U.N., <http://faostat.fao.org/beta/en/#country/231> [<https://perma.cc/7DNN-8EZK>].

same periods dropped from 73 grams to 70 grams.³⁹ If the largest economy in the world has seen dwindling supplies of protein, particularly animal protein, then the developing world has little chance of success. As climate change effects increase, animal protein production is likely to decrease. Additionally, because any increase in traditional livestock production would only increase the effects of climate change, which would negatively impact the food supply, feeding the world’s exponentially expanding population is a significant challenge.

Cultured meat, however, may be able to resolve some of these issues. A substantial decrease in livestock production would have a corresponding decrease on land and water usage. The land used to grow livestock and livestock feed can be set aside for other uses, such as agricultural production for human consumption or reversion back to forest or wetlands. The acres set aside for reforestation or reversion to wetlands would act as a carbon sink. Not only would they eliminate emissions previously produced by that same acreage, they would also further offset GHG emissions. Acres newly devoted to production of agriculture for human consumption could be sustainably farmed and increase agricultural production to the levels needed to feed the world’s growing population, without destroying more forests or ecosystems. And once cultured meat is scaled to an economically sustainable level, one in which the production costs and profit can be covered by the market value, cultured meat can be expanded into developing nations. International funding, perhaps through Clean Development Mechanisms or the World Food Bank, could get laboratories up and running in areas of the world where traditional livestock production is not available. Thus, cultured meat shows promise in mitigating climate change and efficiently producing enough food for the world.

C. Human Health Issues

To aid in reaching specified nutritional, texture, and taste

³⁹ *Id.*

parameters in traditional production, added antibiotics, steroids, and growth hormones are commonly used on livestock farms. These additions are considered necessary to reduce the instances of illness among the herds and to encourage cost-effective rapid growth. Sales of antibiotics for preventative use in livestock are estimated to have gone up by 23 percent from 2009 to 2014, according to the Food and Drug Administration (FDA).⁴⁰ This use of preventative antibiotics also contributes to the growing number of antibiotic-resistant bacteria, including those dangerous to humans.⁴¹ Cultured meat does not require the use of antibiotics because the meat is grown in a bacteria-free environment.⁴² Additionally, cultured meat requires much less processing as it does not need to be slaughtered and separated from the non-edible portions of the animal. This keeps the processing costs of cultured meat low. Growing only those portions of meat that humans eat has benefits; cultured meat does not require the addition of growth hormones to stimulate a presumably cost-effective rate of growth.⁴³ Hormones can be removed from the process, thereby eliminating their harmful effects. Such adverse effects of hormones on human health, according to a report from a European Commission, include “developmental, neurobiological, genotoxic and carcinogenic effects.’ One of these hormones, estradiol, has been banned in farm animals in Europe since 2003 but is still in use in the United States.”⁴⁴

An additional benefit of growing meat in a lab rather than a traditional livestock farm is that those components that make red meat harmful to human health may be eliminated.⁴⁵ Red meats are classified as “‘probably carcinogenic to humans’ and processed meats as ‘carcinogenic to humans.’”⁴⁶ The

40 Memphis Meats Press Release, *supra* note 34.

41 Zaraska, *supra* note 36.

42 *Id.*

43 *Id.*

44 *Id.*

45 *Id.*

46 *Id.*

International Agency for Research on Cancer suggested people “further support public health recommendations to limit intake of meat.”⁴⁷ One of the meat components pinpointed by scientists as contributing to an increased risk of cancer is heme iron, which is a particular type of iron found almost exclusively in meat.⁴⁸ It creates potent carcinogens, such as N-nitroso compounds, and damages DNA in the human body.⁴⁹ It is also linked to increased risk of both breast and colon cancer.⁵⁰ This harmful component, although currently part of our essential protein intake, is absent in cultured meat as blood circulation, where the protein is found, is unnecessary.⁵¹ The consumption of saturated fat, which increases the risk of stroke or heart disease, can also be eliminated.⁵² Cultured meat even requires much less of the preservatives nitrite and nitrate, which are potentially carcinogenic.⁵³ As scientists continue to identify the harmful components of meat, cultured meat labs will be able to attempt to reduce or eliminate them in their products. Some of these potentially harmful components will need to remain, however, to keep cultured meat cooking and tasting like traditional meat.⁵⁴

III. HOW SHOULD CULTURED MEAT BE REGULATED?

Meat around the world is monitored for quality and safety, from international organizations such as the Hazard Analysis and Critical Control Point approach and Codex Alimentarius to domestic organizations like the United States’ FDA and USDA.⁵⁵ Because meat spoils so easily, most governments impose

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ HACCP, FOOD & AGRIC. ORG. OF THE U.N., ANIMAL PRODUCTION & HEALTH, http://www.fao.org/Ag/againfo/themes/en/meat/quality_haccp.html [https://perma.cc/Q457-R86P] (last updated Nov. 25, 2014).

regulations to ensure consumer safety.⁵⁶ This paper avoids the nuances of international meat regulation and instead investigates regulation of meat in the United States to determine where and how cultured meat fits into the existing FDA and USDA regulatory structure.

The FDA must declare a product safe before it is introduced into the market. This paper walks through the different methods in which the FDA may choose to examine the safety status of cultured meat. It also concludes that, should the FDA declare cultured meat safe, the USDA should oversee its day-to-day regulation and marketing.

A. FDA Regulation

The FDA, through the Food, Drug, and Cosmetics Act of 1938, regulates adulterated or misbranded food.⁵⁷ The FDA has previously approved at least two cellular agriculture products, insulin and rennet (an enzyme used in cheese production).⁵⁸ Because insulin is regulated under the drug provisions, it is irrelevant to a discussion of regulation of cultured meat in the food provisions. Rennet, however, is regulated under the FDA provision for a food additive. It was traditionally harvested from the lining of a calf's fourth stomach and so was regulated as an animal product.⁵⁹ And even though it is now made only from a collection of DNA cells, it is still regulated by the FDA. The difference between Rennet and cultured meat, however, is that Rennet is an enzyme that goes into a product that is later inspected and certified. Cultured meat is an end product that would require inspection and certification.

1. Food Additive

Most new food products, such as the enzymes previously

⁵⁶ *Id.*

⁵⁷ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012).

⁵⁸ NEW HARVEST, *supra* note 4.

⁵⁹ *Id.*; 7 C.F.R. § 54.1 (2016).

mentioned and other additives, pass through regulation by being deemed substantially equal to existing products that have already qualified as safe.⁶⁰ Some authors, including the award-winning Zachary Schneider, suggest that cultured meat (or, as he refers to it, in-vitro meat) should be regulated under the exception for foods deemed “generally recognized as safe” (GRAS).⁶¹ Products labeled GRAS are those that meet the “substantially equivalent” standard.⁶² The substances listed in 21 C.F.R. §§ 182.10–182.1810, 184.1005–184.1895 are all added to food, such as spices or preservatives, rather than consisting of a food itself.

Additives are defined as “all substances . . . , the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food.”⁶³ The First Circuit has held that black currant oil, despite being encapsulated in gelatin, is not a food additive, but rather a food itself.⁶⁴ The Court established that, to determine whether a substance is a food or a food additive, one must analyze its intended use.⁶⁵ If the substance is intended to be used by itself, then it is a food.⁶⁶ If the substance is intended to be used only for its effect on another substance, then it is a food additive.⁶⁷

Cultured meat is not added to food, it is the food. Therefore, the provision for food additives is not applicable.

60 Elizabeth Devitt, *Artificial Chicken Grown From Cells Gets A Taste Test-But Who Will Regulate It?*, SCI. MAG. (Mar. 15, 2017),

<http://www.sciencemag.org/news/2017/03/artificial-chicken-grown-cells-gets-taste-test-who-will-regulate-it> [<https://perma.cc/95LT-LSHR>].

61 Zachary Schneider, Comment, *In Vitro Meat, Space Travel, Cannibalism, and Federal Regulation*, 50 HOUS. L. REV. 991, 1006 (2012).

62 *Id.*

63 21 C.F.R. § 170.3(e)(1) (2016).

64 U.S. v. 29 Cartons *** an Article of Food, 987 F.2d 33, 36 (1st Cir. 1993).

65 *Id.* at 36–37.

66 *Id.* at 37.

67 *Id.*

2. Food

The FDA will only govern cultured meat if it meets one of the definitions of FDA covered products. And even though cultured meat does meet the definition of food as it is an “article[] used for food or drink for man or other animals . . . ,” it may not fit in any relevant subcategories.⁶⁸

Cultured meat cannot be a dietary supplement because it is not intended to supplement the human diet, but rather to replace a significant portion of that diet.⁶⁹ It also does not fit well into the meat category, which the FDA defines as “[t]he edible part of the muscle of an animal . . . and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing.”⁷⁰ Because cultured meat is not grown as a result of the lifecycle of an animal, this definition is inapplicable. The only portions of an animal used in cultured meat are a few of the original cells from the animal’s muscle, which are then grown in a petri dish.

Nor does cultured meat fall under the definition of “meat by-product” under the FDA regulations. “Meat by-product” is intended to catch ancillary portions of the animal not captured under the “meat” definition, and examples include “livers, kidneys, sweetbreads, brains, lungs, spleens, stomachs, tripe, lips, snouts, and ears.”⁷¹ Cultured meat could possibly fall under the definition of meat products, which is defined as “[a]ny articles intended for human food . . . which are derived or prepared in whole or *in substantial and definite part*, from any portion of any animal”⁷² However, the individual cells procured from the animal do not rise to the level of a

68 21 U.S.C. § 321(a)(2)(f) (2012).

69 21 U.S.C.S. § 321(ff) (2012).

70 7 C.F.R. § 54.1 (2016).

71 *Id.*

72 *Id.* (emphasis added).

“substantial and definite part” required.⁷³ Therefore, the FDA may not currently have a definition that applies to cultured meat. The Secretary of the FDA, however, can introduce one and apply standards to that definition.⁷⁴

B. USDA Regulation of Genetically-Modified Organisms

Another possibility for regulation is under the USDA’s provisions for genetically modified organisms (GMOs) because such regulations already account for products produced in a laboratory. Current regulations cover GMO crops such as corn and soybeans. The problem with applying these regulations to cultured meat, however, is that they are designed specifically for plants and analyze any modifications only to identify potential plant pests.⁷⁵ Once GMOs are determined safe for plants rather than considered invasive species, they are rolled into commercial production as any other crop.⁷⁶ They are considered “de-regulated” and are no longer held to specialized inspection or labeling concerns.⁷⁷ This is similar to the FDA’s GRAS standards for food additives.

While cultured meat is grown in a lab and could potentially be genetically altered to produce a desirable breakdown of nutrients, it has not yet undergone such modification. There are other challenges to being regulated as genetically modified under the FDA provision for plant pests. Significantly, cultured meat is not a potential plant pest. It is grown in a lab, not a field, and it poses no danger of becoming an invasive species. However, if the regulations were expanded, the USDA’s process of investigating the safety of GMO crops could be used to similarly determine the

73 See 21 U.S.C. § 601(j) (2012) (excluding “relatively small proportion or historically have not been considered by consumers as products of the meat food industry” from the meat product definition).

74 21 U.S.C. § 341 (2012).

75 Rita Barnett-Rose, *Judicially Modified Democracy: Court and State Pre-emption of Local GMO Regulation in Hawaii and Beyond*, 26 DUKE ENVTL. L. & POL’Y F. 71, 85 (2015); 7 C.F.R. § 340.2 (2012).

76 Barnett-Rose, *supra* note 75, at 85–87.

77 *Id.* at 86; Schneider, *supra* note 61, at 1007.

safety of cultured meat.

Another potential location for cultured meat regulations is the Federal Meat Inspection Act (FMIA).⁷⁸ This should be possible because similar provisions such as GRAS are already present in different sections of both USDA and FDA regulations. These cultured meat regulations would function similarly to the plant pest provisions and serve the same purpose: ensuring safety for the human diet. Because of the similarities in cellular modification, each modification could undergo the same investigative process. A group of investigators would observe test batches for any harmful results. Once certified, it could also be “de-regulated” and treated as any other meat product. The USDA is another option for certification for the primary regulation of non-genetically modified cultured meat.

C. FDA Regulation of New Animal Drugs

The USDA is another option for certification for the primary regulation of non-genetically modified cultured meat. One of the most bizarre examples of regulatory shoehorning is the FDA’s use of the New Animal Drug Application (NADA) and its complimentary provisions to regulate genetically modified animals. Currently, cultured meat does not qualify as genetically modified because the DNA is not altered. Should modifications occur in the future, however, the FDA’s current attempts to regulate genetically modified animals could encapsulate cultured meat. The potential modification of cultured meat to create an ideal nutrient balance would fall under this proposed approach to regulation.

According to Schneider, the FDA views the manipulation of DNA as included under the 21 U.S.C. § 321(g)(1)(C) definition of “drug.”⁷⁹ The FDA equates the practice of giving animals drugs to change their body composition, such as hormones, with changing the nutrient composition of meat through genetic

⁷⁸ Federal Meat Inspection Act, 21 U.S.C. §§ 601–695 (2012).

⁷⁹ Schneider, *supra* note 61, at 1010.

manipulation.⁸⁰ This provision could also be used to regulate the manufacturing process of cultured meat.⁸¹ The biggest issue with using drug provisions to regulate cultured meat is that meat requires different and quality standards than do drugs. Because the USDA promulgates the qualifications for meat, regulating cultured meat under the FDA’s drug provisions would ensure that cultured meat would not be competitive with traditional meat. The labeling, packaging, standards, and other considerations for traditional meat would not be applied to cultured meat if regulated by the FDA as those regulations are only for products falling under the USDA. Therefore, to ensure the best combination of regulations and a competitive product, cultured meat should be inspected and certified by the USDA.

D. FDA’s Biotechnology Regulations

The federal government recently proposed a new Update to the Coordinate Framework for the Regulation of Biotechnology (Framework) on September 16, 2016.⁸² Otherwise, the most recent update was in 1992.⁸³ Biotechnology has changed a great deal since that time, however, and this proposed updated Framework provides a better way to determine and regulate the safety of biotechnologies, including cultured meat.

The new Framework includes graphical illustration overviews of the regulatory roles of different agencies, case studies to help developers navigate the regulations, and a comprehensive table of responsibility and coordination summaries of the regulations.⁸⁴ The proposal suggests that NADA provisions should regulate genetically engineered animals.⁸⁵ This proposal,

80 *Id.*

81 *Id.* at 1011.

82 *Id.*

83 *Id.*

84 *Id.*

85 THE WHITE HOUSE, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY,

however, does little to change the haphazard nature of current regulations for genetically modified animals. While NADA will be appropriate for future approval of modifications made to cultured meat's nutritional value, current cultured meat has not been genetically modified in the same way. Instead, a new provision allowing a GRAS or other petition for lab-grown tissue for human food should be included in the new regulations. Another possible method is a generalized petition for approval available under this provision for all of those products that do not fit current regulations.

This new provision would silence critics who say that it is dangerous to use provisions that were never designed to accommodate these types of biotechnological advances. Skeptics, concerned with ethical implications, health implications, or both, maintain that such new technologies should be subjected to longer study periods before they are deemed safe for human consumption.⁸⁶ These concerns are similar to those raised by critics of GMO plants. Creating and implementing a generalized petition for safety would allow the FDA to adapt their investigation to the specific needs presented by that biotechnology and study the long-term effects of each new submission. Instead of attempting to apply new drug or food additive provisions to a product that is simply neither, the FDA can pursue the avenues that it deems necessary to ensure that product's safety. This general safety petition would also be available to advancements made decades from now that people cannot reasonably anticipate, just as the development of genetically engineered animals or cultured meat was not foreseen when the Framework was first established.⁸⁷

E. USDA Day-to-Day Regulation of Meat

The USDA, through the FMIA, Poultry and Poultry Products

https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf [https://perma.cc/Q88Z-7838].

⁸⁶ See *id.*

⁸⁷ See *id.*

Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), regulates the ordinary lifecycle of meat.⁸⁸ This paper deals with cultured meat that currently is made from beef cells, so it looks primarily towards the USDA’s regulation of beef in the FMIA. The FMIA regulates “meat food products.”⁸⁹

The term “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, excepting 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 to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products.⁹⁰

Under this definition, cultured meat would not be regulated by the FMIA until the Secretary determines that it is safe and qualifies as a meat food product.⁹¹ Further, unless cultured meat falls under the definition of meat food product, it cannot be regulated by the USDA’s inspection, safety, and quality guidelines. Because cultured meat would be sold as a meat replacement product, not being able to use the label “meat product” is detrimental. The definition as a meat food product is not ideal for cultured meat as cultured meat is intended to have

88 Federal Meat Inspection Act, 21 U.S.C. §§ 601–695 (2012); Poultry and Poultry Products Inspection Act, 21 U.S.C. §§ 451–472 (2012); Egg Products Inspection Act, 21 U.S.C. §§ 1031–1056 (2012); *see* 21 U.S.C. §§ 453(i), 601(a), 1033(x) (all defining “Secretary” as the Secretary of Agriculture).

89 21 U.S.C. § 601.

90 21 U.S.C. § 601(j).

91 21 U.S.C. § 601(j), (m).

the same quality and safety assurances as traditional meat.

F. New Regulation for Cultured Meat

Because the Secretary for the FDA can adopt regulations, s/he would be able to certify the safety of cultured meat and establish its further regulation. Under 21 U.S.C. § 341,

[w]henver in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container.⁹²

The Secretary has the authority to declare products safe and determine their further regulation, which in the past has included the use of cloned animals. In 2008, the Secretary of the FDA concluded that cloned animals and their offspring were safe for human consumption.⁹³ After investigating the use and nature of cloned animals, the FDA observed no abnormalities that would endanger human health.⁹⁴ Additionally, the agency did not promulgate any regulations specifically for cloned animals.⁹⁵ Rather, they were adopted into the existing regulations. This worked for cloned animals because they were still living, breathing livestock that fit the definition of meat and meat product.⁹⁶ This would not be so for cultured meat,.

This paper suggests that the modifications to the Framework should include a generalized petition to allow the regulations the flexibility to accommodate scientific advances, like cultured meat, that do not fit into either food, food additive, GMO, or

⁹² 21 U.S.C. § 341.

⁹³ Schneider, *supra* note 61, at 1008.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *See id.*

NADA provisions. The USDA already has a system in place for day-to-day inspection and classification of meat. Instead of creating a whole new system, or shoehorning cultured meat into existing regulations that are inapt, a generalized petition provision could be used to determine the safety of cultured meat and leave the day-to-day regulation to the USDA.

The FDA’s safety decision would place cultured meat laboratories and factories under the USDA’s supervision of slaughterhouses and traditional factories. Cultured meat production would follow the FMIA safety regulations for a clean and safe workplace. As for the product itself, cultured meat should follow the same dietary regulations and quality assessments as traditional meat under the FMIA. If additional regulations to ensure the safety of cultured meat were needed, the USDA could use its authority to promulgate any necessary changes.⁹⁷

CONCLUSION

The world is facing a series of important issues concerning livestock production. The climate has suffered, and continues to suffer, under traditional practices. The amount of land, water, and energy use needed under traditional livestock practices makes the possibility of expansion questionable. The problem, however, is that expansion of livestock production is necessary to feed the world’s growing population. Assuming production can be expanded to scale, cultured meat has the potential to fix these issues. Studies conducted at Oxford predict a “78–98 percent reduction in greenhouse gas emissions, 99 percent reduction in land use and 82–96 percent reduction in water use, and 45 percent reduction in energy use.”⁹⁸ Cultured meat laboratories or factories producing could be located in areas of the world that do

97 *See id.* at 1011 (the USDA regulates conditions for any surface or tool that contacts meat, the cleaning of places producing meat, the conditions and cleanliness of workers and workplaces for meat, and the quality of the product).
98 de Mattos & Tuomisto, *supra* note 3.

not support traditional livestock operations. The amount of animal protein produced could be expanded to reduce, and possibly eliminate, hunger and protein deficiencies in developing countries and food deserts without increasing GHG emissions. With the costs of meat projected to rise in the next few decades, cultured meat could be a competitive option in the near future.⁹⁹ Although existing regulations may not accommodate cultured meat, adding a supplemental provision to the FDA's meat regulations would allow it to be properly regulated and placed into the market. A generalized petition to determine the safety of products and advancements in technology that do not fit into any other regulatory scheme should be created to avoid future problems with advancing biotechnologies. Trying to force new technology through ill-fitting provisions is an unbecoming way to welcome new biotechnologies. The United States' Framework should learn from the past revisions and introduce an additional safety petition.

⁹⁹ *Mark Post's Cultured Beef*, *supra* note 12.