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THE REGULATION OF LAB-GROWN MEAT UNDER EXISTING JURISDICTIONAL AUTHORITY

KATE SOLLEE*

INTRODUCTION

Consumers in the United States eat around fifty-two billion pounds of meat per year—averaging 270 pounds per person.¹ Traditional agricultural meat production is associated with significant adverse environmental and public health impacts.² With an anticipated seventy percent increase in global meat demand, we will have insufficient planetary resources to provide meat to the world’s population by 2050.³ Thus, it is imperative that human dietary habits change. Namely, we must reduce traditional agricultural meat consumption.⁴

Some consumers opt for vegetarian food, such as vegetable (“veggie”) burgers or plant-based proteins,⁵ but most consumers are not willing to do so.⁶ Cellular meat may be a more consumer-friendly alternative to traditional agricultural meat. Cellular agriculture aims to produce animal proteins using far

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1. Jennifer Penn, *Cultured Meat: Lab-Grown Beef and Regulating the Future Meat Market*, 36 *UCLA J. ENV'T L. & POL'Y* 104, 105 (2018).

2. See Mark J. Post et al., *Scientific, sustainability and regulatory challenges of cultured meat*, 1 *NATURE FOOD* 403, 403 (2020) (explaining the environmental and public health impacts of traditional agricultural).

3. *Id.*

4. See Jennie I. Macdiarmid, Flora Douglas & Jonina Campbell, *Eating like there's no tomorrow: Public awareness of the environmental impact of food and reluctance to eat less meat as part of a sustainable diet*, 96 *APPETITE* 487, 488 (2016) (finding that reducing meat consumption can reduce GHG emissions while achieving dietary requirements).

5. See Rachel E. Santo et al., *Considering Plant-Based Meat Substitutes and Cell-Based Meats: A Public Health and Food Systems*, 4 *FRONTIERS SUSTAINABLE FOOD SYS.* 1, 2 (2020) (stating that “a growing number of people are replacing a share of their meat intake with ‘plant-based substitutes’ that seek to approximate the texture, flavor, and/or nutrient profiles of farmed meat using ingredients derived from pulses, grains, oils, and other plants and/or fungi”).

6. *Id.*

fewer animals and animal-derived materials than the current livestock industry.⁷ Cellular meat is part of an emerging area of biotechnology known as “cellular agriculture,” which uses cell-based biotechnology to replace traditional animal-derived products such as meat, seafood, leather, and milk.⁸ Proponents of cellular agriculture emphasize that the process allows for a more efficient, healthy, sustainable, and predictable food supply.⁹ The concept of cellular meat continues to rise in popularity and can no longer be disregarded as a far-fetched idea. Major agricultural corporations, including Cargill and Tyson, have invested in the technology.¹⁰ Bill Gates also identified lab-grown meat as one of ten breakthrough technologies of 2019.¹¹

However, as a novel emerging biotechnology, cellular meat presents a multitude of regulatory issues.¹² With no legally binding regulatory structure in place, the threshold issue remains: what regulatory scheme *should* be used to govern cellular meat, consistent with the existing legal framework? The way that cellular meat is regulated will be a critical factor in the product’s acceptance by consumers.¹³

Section I of this article introduces relevant background information on cellular meat, including how cellular meat is made, its environmental and public health benefits, its negative aspects, and regulatory issues.¹⁴ Section II considers the existing legal framework, including current statutory authorities and regulatory programs for human food.¹⁵ Section III then analyzes the question of which federal agency or agencies *should* regulate cellular meat, from two perspectives: first, which agencies are the most appropriate regulators based on existing statutes and regulatory authority?; and second, which agencies are the most appropriate from a policy perspective?¹⁶

7. See Margaret Rosso Grossman, *USDA and FDA Formal Agreement on Regulation of Cultured Meat*, 14 EUROPEAN FOOD & FEED L. REV. 385, 385 (2019) (stating that “for consumers who prefer animal proteins . . . cellular agriculture may offer innovative proteins that resemble traditional products of livestock”).

8. Post et al., *supra* note 2, at 403.

9. Amaru Sanchez, *Laws and Regulations Concerning Cell-Cultured Meat and Cellular Agriculture*, FOOD & DRUG L. INST. (FDLI), <https://www.fdpi.org/2018/02/update-laws-regulations-concerning-cell-cultured-meat-cellular-agriculture/> (last visited Nov. 28, 2020).

10. Grossman, *supra* note 7, at 385.

11. *Id.*

12. *Id.* at 386.

13. Grossman, *supra* note 7, at 389.

14. See *infra* Section I.

15. See *infra* Section II.

16. See *infra* Section III.

I. BACKGROUND

A. The Production of Cellular Meat

The biotechnology behind cellular meat has developed over the past three decades into a multistep process.¹⁷ Stem cells enable the manufacturing of cellular meat, as they can be isolated from a living animal and cultivated in vitro to generate a multitude of different cell types.¹⁸

To start the cellular meat-making process, stem cells are obtained from the target animal, generally through a biopsy method.¹⁹ Specifically, the cells are harvested from mature muscle tissue and adipose tissue of the animal.²⁰ The stem cells are then cultivated in a nutrient-rich medium under controlled conditions.²¹ The cell culture is initially performed in petri dishes or flasks and is then transferred to bioreactors as the cells continue to multiply.²² Bioreactors are crucial in automating the labor-intensive parts of the process to reduce overall cost and risk of contamination.²³ The ultimate goal of bioreactor development is to maximize the percentage of nutrients in the culture medium that is to be converted into edible animal tissue.²⁴

Within the bioreactor, the cells are cultivated around biomaterial scaffolds.²⁵ The scaffolds give support and three-dimensional organization to the cells, so that the tissue assembles to resemble meat in both its sensory and nutrient qualities.²⁶ Stem cells are stimulated to differentiate into muscle or other types of specialized cells using biochemical signals that are supported by electrical or mechanical stimulation of the growing tissue.²⁷ To generate products that replicate the properties of meat, the technology produces an accurate balance of muscle, fiber, fat, bone, and cartilage tissue.²⁸

17. Walter G. Johnson, *Conflict over Cell-Based Meat: Who Should Coordinate Agencies in U.S. Biotechnology Regulation*, 74 FOOD & DRUG L.J. 478, 481 (2019).

18. *Id.*

19. *Id.*

20. Post et al., *supra* note 2, at 404.

21. Johnson, *supra* note 17.

22. Post et al., *supra* note 2, at 406.

23. Bioreactors provide a means for scalability, controllability (in temperature, pH, dissolved oxygen, and carbon dioxide levels), and high achievable cell densities. *Id.*

24. In other words, to maximize the medium conversion ratio, which is equivalent to the feed conversion ratio (mass of feed per mass of resulting meat) in traditional livestock meat production. *Id.*

25. *Id.* at 403.

26. *Id.*

27. Johnson, *supra* note 17, at 481–82.

28. *Id.* at 482.

*B. The Promise of Cellular Meat**1. Environmental Damage Caused by Traditional Agricultural Meat*

Traditional meat production is associated with a significant adverse environmental impact and is undoubtedly contributing to climate change.²⁹ Livestock production accounts for approximately 18% of global greenhouse gas (GHG) emissions, more than either transportation or energy production.³⁰ Livestock production is responsible for some of the most potent and heat trapping GHGs, accounting for 37% of anthropogenic emissions of methane, 65% of anthropogenic nitrous oxide emissions, and 64% of anthropogenic ammonia emissions.³¹

Livestock production is also the largest anthropogenic use of land, with 30% of the planet's total land and 70% of its arable land devoted to livestock production.³² Data from a 2012 land-use survey indicated that in the United States—which has a total of about 1.9 billion acres—livestock grazed on almost 800 million acres, and more than 200 million acres of crop land were used to produce feed.³³ Notably, livestock production also accounts for 8% of global human water use.³⁴

Moreover, traditional animal agriculture operations produce large quantities of waste, including manure, urine, carcasses, and excess feed.³⁵ Serious environmental problems result from these operations, and more waste is produced than can be used as fertilizer.³⁶ Storage pits for waste piles leak their contents into groundwater and streams, contaminating the water.³⁷ Waste from storage pits are often spread or sprayed on land, and this application can pollute air and water.³⁸ Levels of phosphorous and nitrogen in the waste exceed what crops can utilize or the soil can retain, and excess nutrients contaminate surface waters and streams, causing eutrophication of nearby water bodies, dead zones,

29. Neus Gonzáles et al., *Meat consumption: Which are the current global risks? A review of recent (2010–2020) evidences*, 137 FOOD RSCH. INT'L 1, 1 (2020).

30. Penn, *supra* note 1, at 110.

31. *Id.*

32. *Id.*

33. Daniel P. Bigelow & Allison Borchers, *Major Uses of Land in the United States, 2012*, EIB 178, USDA ECONOMIC RES. SERV. (2017).

34. Penn, *supra* note 1, at 110.

35. ENV'T PROT. AGENCY, ENVIRONMENTAL ASSESSMENT OF PROPOSED REVISIONS TO THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM REGULATION AND THE EFFLUENT GUIDELINES FOR CONCENTRATED ANIMAL FEEDING OPERATIONS 2 (Jan. 2001).

36. CARRIE HRIBAR, NAT'L ASS'N LOC. BDS. OF HEALTH, UNDERSTANDING CONCENTRATED ANIMAL FEEDING OPERATIONS AND THEIR IMPACT ON COMMUNITIES 1 (Mark Shultz ed., 2010).

37. *Why are CAFOs so bad?*, SIERRA CLUB MICH. CHAPTER, <https://www.sierraclub.org/michigan/why-are-cafos-bad> (last visited Nov. 28, 2020).

38. *Id.*

and degradation of coral reefs.³⁹ Additionally, land used for livestock production is highly susceptible to over-grazing, compaction, and erosion.⁴⁰ Within the United States alone, livestock production causes 55% of all land erosion.⁴¹

While many environmental damage mitigation strategies focus on improving efficiency, technological advances, and reducing waste in food production, it is increasingly recognized that these strategies alone are insufficient to meet GHG emission-reduction and other environmental conservation targets. Even if all parties involved in traditional animal agriculture used best available practices, environmental degradation would still be too high to meet conservation goals.⁴²

2. Environmental Benefits of Cellular Meat

Given the negative consequences of traditional agricultural meat production, the Intergovernmental Panel on Climate Change emphasized the need to substantially reduce our consumption of conventional animal products.⁴³

The potential benefits to the planet are significant; a switch to cellular meat could save up to 99% of the land, 90% of the water, and 45% of the energy that is currently devoted to traditional agricultural steak, sausage, and bacon production.⁴⁴ Additionally, fossil fuel energy used for traditional agricultural meat could be almost cut in half;⁴⁵ one calorie of cellular meat requires only three calories of input.⁴⁶ This is an 87% decrease in the amount of energy needed to create one calorie of traditional agricultural meat.⁴⁷ Furthermore, if cellular meat were substituted for ground beef, United States consumers could save 26.8 pounds of feed per person, which could be repurposed to feed the growing population or to create ethanol.⁴⁸ This would also free up 167.6 gallons of water and 3455 square feet of land per consumer that could be reforested or reclaimed for natural landscape and carbon sinks, or to produce food for the world's growing population.⁴⁹

39. Penn, *supra* note 1, at 110–11.

40. *Id.*

41. *Id.* at 111.

42. *Id.* at 110.

43. Post et al., *supra* note 2, at 403.

44. Penn, *supra* note 1, at 111.

45. *Id.* at 106.

46. *Id.* at 111.

47. *Id.* at 106.

48. *Id.*

49. *Id.*

3. *Public Health Dangers Associated with Traditional Agricultural Meat*

Preventative antibiotics, steroids, and growth hormones are commonly used on livestock farms.⁵⁰ These additions are necessary in the industrial agricultural system—where a large number of animals are grown and processed in heavy concentrations—to reduce the instances of illness among the herds and to facilitate cost-effective rapid growth.⁵¹ Unfortunately, the additions are also detrimental to public health.

The use of preventative antibiotics in traditional animal agriculture contributes to the growing number of antibiotic-resistant bacteria, including those dangerous to humans.⁵² Sales of antibiotics for preventative use in livestock are estimated by the Food and Drug Administration (FDA) to have gone up by 23% from 2009 to 2014.⁵³ Additionally, the Union of Concerned Scientists estimates that more than 70% of all antibiotics produced in the United States are used in animal production.⁵⁴ Since many of these antibiotics are closely related to those used to treat human infections, antibiotic-resistant strains of bacteria that develop in animals threaten the usefulness of these medicines in treating humans.⁵⁵

Additionally, some growth hormones used in traditional animal agriculture are shown to have adverse effects on human health.⁵⁶ Specifically, these hormones may cause developmental, neurobiological, genotoxic, and carcinogenic effects.⁵⁷ One common growth hormone, estradiol, has been banned from use on farm animals in Europe since 2003 but is still utilized in the United States.⁵⁸

As previously discussed, traditional animal agriculture also generates a vast amount of waste.⁵⁹ This waste not only damages the environment, but also creates many public health risks as animal feeds, additives, manure, and carcass by-products frequently contaminate human food.⁶⁰ Feed contaminants such as arsenic and other heavy metals, nitrogen, and phosphorus pass through the animal directly into manure, creating risks to soil and water quality.⁶¹ The same

50. *Id.* at 114.

51. *Id.*

52. *Id.*

53. *Id.*

54. Polly Walker et al., *Public Health Implications of Meat Production and Consumption*, 8 PUB. HEALTH NUTRITION 348, 352 (2005).

55. *Id.*

56. Penn, *supra* note 1, at 114.

57. *Id.*

58. *Id.*

59. *See supra* Section I.B.i.

60. Walker et al., *supra* note 54, at 351.

61. *Id.* at 352.

is true of antibiotics, steroids, and growth hormones.⁶² Organic dust, bacterial endotoxins, and manure-generated compounds such as ammonia and hydrogen sulfide are also found in animal wastes.⁶³ Additionally, these wastes contain pathogens that can cause potentially fatal infections in humans, such as Salmonella, Listeria Campylobacter, and Cryptosporidium.⁶⁴

Lastly, red meats are high in saturated fat, which increases risk of a stroke and heart disease.⁶⁵ Red meats are also classified as “probably carcinogenic to humans.”⁶⁶ Scientists have identified heme iron, a type of iron found almost exclusively in meat, as contributing to an increased risk of cancer.⁶⁷ Heme iron creates potent carcinogens, like N-nitroso compounds, and thereby damages human DNA.⁶⁸

4. Public Health Benefits Associated with Cellular Meat

Cellular meat avoids several public health challenges associated with traditional agricultural meat. Because far fewer animals are needed to produce the same amount of meat, animal waste and some of the other negative public health consequences discussed in the preceding subsection are significantly reduced. In addition, some of the harmful components of traditional agricultural meat are not found in cellular meat.⁶⁹ For instance, heme iron—which creates known human carcinogens—is absent in cellular meat.⁷⁰ Likewise, saturated fat can be reduced or eliminated from meat during the cellular meat growth process.⁷¹ As scientists continue to identify the harmful parts of meat, cultured meat labs may have the ability to reduce or eliminate these harms in their products.⁷² Finally, cellular meat requires fewer preservatives such as nitrate and nitrite, which are also potentially carcinogenic.⁷³

5. Negative Aspects of Cellular Meat

Despite the positive features of cellular meat when compared with traditional animal agriculture, some aspects may nonetheless be problematic. For

62. *Id.*

63. *Id.* at 353.

64. *Id.*

65. *Id.* at 354.

66. Penn, *supra* note 1, at 114.

67. *See id.* at 115 (noting that heme iron is linked to higher risks of developing both breast and colon cancer).

68. *Id.*

69. *Id.* at 114.

70. *Id.* at 115.

71. *Id.*

72. *Id.*

73. *Id.*

one, lab sterility is a significant issue.⁷⁴ Animals have an immune system that works to protect them against bacterial infection; cell cultures do not.⁷⁵ In a nutrient-rich environment, bacteria multiply far faster than animal cells do.⁷⁶ Since a high level of sterility is required to avoid contamination,⁷⁷ cellular meat production may require antibiotics or extreme energy costs and/or plastic waste to maintain sterility.⁷⁸ For example, to avoid contamination, the bioreactors used to grow meat cells in many labs are typically single-use plastics.⁷⁹ To put this into perspective, capturing only one tenth of one percent of the global meat market would require over fifteen thousand of these single use plastic tanks.⁸⁰ The energy costs associated with the infrastructure might also be extremely high in the long term.⁸¹ While only a few studies have been conducted on the environmental impact of the pharmaceutical industry, available data suggests that its carbon footprint may be significantly higher than that of the automotive industry.⁸² Lastly, muscle volume increases slowly, and continuous supplies of “natural growth factors,” including hormones, may be necessary to speed up proliferation of cells in the lab.⁸³

C. Regulatory Issues Associated with Cellular Meat

As a novel emerging biotechnology, cellular meat presents a multitude of regulatory issues. First, production, harvesting, and marketing oversight processes must be established. Second, the government needs to determine which federal agencies should have oversight authority over these processes.

1. Cellular Meat Oversight Issues: Production, Harvesting, Marketing, and Labeling

The production, harvesting, marketing, and labeling of cellular meat is a complicated multi-step process. The first set of regulatory questions involve the appropriate nature and scope of the production oversight process: what standards

74. Eric Muraille, ‘Cultured’ meat could create more problems than it solves, THE CONVERSATION (Nov. 28, 2019, 1:27 PM), <https://theconversation.com/cultured-meat-could-create-more-problems-than-it-solves-127702>.

75. *Id.*

76. *Id.*

77. *Id.*

78. Chriki Sghaier & Jean-François Hocquette, *The Myth of Cultured Meat: A Review*, 7 FRONTIER NUTRITION 1, 1, 2 (2020).

79. Sam Bloch, *The hype and the hope surrounding lab-grown meat*, THE COUNTER (July 23, 2019, 4:51 PM), <https://thecounter.org/new-harvest-cell-cultured-meat-lab-meat/>.

80. *Id.*

81. Neil Stephens et al., *Bringing cultured meat to market: Technical, socio-political, and regulatory challenges in cellular agriculture*, 78 TRENDS IN FOOD, SCI. & TECH. 155, 157–58 (2018).

82. Muraille, *supra* note 74.

83. *Id.*

will govern lab safety and cleanliness?; what standards will govern ingredients?; what will be the timeline of review?; will there be affirmative approval of cellular meat ingredients and products, as opposed to just the absence of any objections?; will approval, through either an active or passive process, be attached to a particular production facility, or will it be attached to a particular process, or some other distinction? The answers to these questions remain uncertain.

Similarly, there are several questions about appropriate oversight of the harvesting and marketing processes. For example, an already-controversial issue is how cellular meat products will be inspected and labeled: should the word “meat” even appear on the labeling? Can cellular meat products maintain access to the terminology applied to traditional agricultural meat, such as sausage, meatball, or ground beef? If cellular meat is called artificial muscle proteins, will that scare away consumers? Once again, the answers to these questions remain up for debate.

In 2018, the United States Cattlemen’s Association, a lobbying organization, petitioned the United States Department of Agriculture Food Safety and Inspection Service (USDA-FSIS) for a regulation that would require clear labeling and identification of “beef” products not derived from cattle.⁸⁴ The association requested that the USDA-FSIS define meat as “the tissue or flesh of animals that have been harvested in the traditional [agricultural] manner,” such that cellular meat could not be marketed as “meat.”⁸⁵ Contrarily, proponents of cellular meat assert that since the finished product has characteristics identical to traditional meat products, it can be identically labeled. The Good Food Institute (GFI), an advocacy group for plant-based foods and cell-cultured meat, argues that cellular meat products should be labeled “clean meat.”⁸⁶ GFI maintains that “clean meat” is a more accurate way of describing real meat grown without animal slaughter, and that “clean meat” is similar to “clean energy” in that it immediately communicates important aspects of the technology, including the environmental benefits and the decrease in food-borne pathogens and drug residues.⁸⁷

Complicating matters, there has been a wave of recent legislative activity in states with significant livestock industries, advancing the view that traditional meat terminology should be used only for products derived from carcasses of once-live animals.⁸⁸ In other words, these states propose that cellular meat should

84. Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells, 86 Fed. Reg. 49491 (proposed Sept. 3, 2021) (to be codified at 9 C.F.R. chapter undefined).

85. *Id.*

86. JOEL L. GREENE & SAHAR ANGADJIVAND, CONG. RSCH. SERV., IF10947, REGULATION OF CELL-CULTURED MEAT (2018).

87. *Id.*

88. Robert Hibbert & Amaru Sanchez, *State Meat Label Restrictions Face Preemption Challenges*, LAW 360 (Mar. 6, 2019, 2:37 PM), <https://www.law360.com/articles/1135648/state-meat-label-restrictions-face-preemption-challenges> [hereinafter Hibbert & Sanchez I].

not be labeled as meat, ground beef, or anything of the like. Under Louisiana’s law, “meat” specifically excludes anything that is a “cell-cultured food product grown in a laboratory from animal cells.”⁸⁹ Similarly, a new law in Missouri states that for a product to be called “meat,” it has to come from a real animal.⁹⁰ Some state proposals even go so far as to criminalize the labeling of food products inconsistent with the states’ new definitions.⁹¹

2. Federal Preemption

It is unclear whether these state initiatives would withstand a legal challenge on federal preemption grounds.⁹² Language in the Federal Meat Inspection Act (FMIA) explicitly declares that states cannot impose marketing, labeling, and ingredients requirements that are “in addition to, or different than” those required under the FMIA.⁹³ This rule attaches to all USDA-regulated products and has been used consistently by the meat industry to fight various state initiatives that the industry opposes.⁹⁴ For example, in *Armour v. Ball*,⁹⁵ meat producers brought an action against state officials of Michigan averring a conflict between state and federal law,⁹⁶ arguing that the marketing, labeling, packaging, and ingredient provisions of the Michigan statute were “in addition to, or different than” rules established by the federal regulation and thus preempted under 21 U.S.C.A § 678 and the Supremacy Clause (Article VI, Clause 2) of the United States Constitution.⁹⁷ The Sixth Circuit held that under the Supremacy Clause, the FMIA preempted the parts of the Michigan law regarding the transportation and commercial sale of meat food products, and that, additionally, the marketing, labeling, and ingredient requirements of the federal regulations preempted analogous provisions of the Michigan law.⁹⁸ Thus, it seems likely—based on the explicit language of the FMIA—that cellular meat products would fall within the protective umbrella of labeling preemption under the FMIA.⁹⁹

89. Zoë Corbyn, *Out of the Lab and Into your Frying Pan: The Advance of Cultured Meat*, THE GUARDIAN (Jan. 19, 2020, 4:00 PM), <https://www.theguardian.com/food/2020/jan/19/cultured-meat-on-its-way-to-a-table-near-you-cultivated-cells-farming-society-ethics>.

90. Hibbert & Sanchez I, *supra* note 88.

91. *See id.* (naming Arizona, Arkansas, Colorado, Indiana, Mississippi, Missouri, Nebraska, North Dakota, Washington, and Wyoming as states who are already pursuing these initiatives).

92. *Id.*

93. 21 U.S.C § 678.

94. Hibbert & Sanchez I, *supra* note 88.

95. *Id.*; 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973).

96. *Id.*

97. Hibbert & Sanchez I, *supra* note 88; *Armour*, 468 F.2d at 76.

98. Hibbert & Sanchez I, *supra* note 88.

99. *Id.*

Another impediment to state efforts may be the Food Drug and Cosmetic Act (FDCA), amended by the Nutrition Labeling and Education Act. The Act expressly states that “no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for the labeling of food of the type required by [nearly every subsection of Section 343] that is not identical to the requirement of such section.”¹⁰⁰ This statute has frequently been successfully invoked for food products regulated by the FDA.¹⁰¹ For example, in *Regan v. Sioux Honey Association Cooperative*,¹⁰² a Wisconsin law did not allow a food product to be labeled “honey” if the pollen was removed.¹⁰³ The Sioux Honey Association Cooperative argued that although its product did not contain pollen, they were required under federal law to identify the food as “honey,” its common or usual name, on the product label.¹⁰⁴ The court agreed and held that the Wisconsin law was preempted because it “impose[d] a requirement which is not imposed by federal law and is therefore not identical to the federal law.”¹⁰⁵

Some courts, however, have specified that federal preemption under the FDCA does not automatically apply to every kind of state-imposed food labeling requirement. For instance, in *Cortina v. Goya Foods Inc.*,¹⁰⁶ the court held that federal preemption does not apply to state labeling requirements concerning carcinogens in food.¹⁰⁷ And in *Garcia v. Kashi Co.*,¹⁰⁸ the court held that federal preemption did not apply to a state law regarding “natural” food labeling claims.¹⁰⁹ Noting these discrepancies, however, the general trend is that a court will find federal preemption if the label or statement at issue is directly governed by the terms of the FDCA.¹¹⁰

3. Agency Jurisdiction

In addition to deciding how cellular meat should be regulated, an important issue to consider is which federal agency or agencies should have oversight authority over the various regulatory issues. The first question is whether the law already clearly allocates oversight jurisdiction to a particular agency. As discussed below, there is some disagreement among experts on the answer to that question. Accordingly, this Subsection I.C.ii. will examine which agency or

100. 21 U.S.C. § 343-1(a)(1)-(5); Hibbert & Sanchez I, *supra* note 88.

101. Hibbert & Sanchez I, *supra* note 88.

102. 921 F. Supp. 2d 938 (E.D. Wis. 2013).

103. *Id.* at 941.

104. *Id.* at 942.

105. *Id.* at 943.

106. 94 F. Supp. 3d 1174 (S.D. Cal. 2015).

107. *Id.* at 1188.

108. 43 F. Supp. 3d 1359 (S.D. Fla. 2014).

109. *Id.* at 1371–74.

110. Hibbert & Sanchez I, *supra* note 88.

agencies *should* have responsibility over the various aspects of cellular meat production and marketing.

The following questions should be analyzed when making decisions regarding agency jurisdiction of cellular meat: at the production stage, which federal agency is best equipped to regulate the numerous inputs in the production of cellular meat?; how will individual technicalities of the cell meat process be governed?; what agency has the resources to be an effective regulator?

A particularly pressing issue in this area is how growth serum used in the cellular meat process will be governed. Currently, the industry largely relies on fetal bovine serum (FBS),¹¹¹ its obtention involving the extraction of blood from the fetus of a cow immediately after a mother is slaughtered for meat processing.¹¹² In other words, FBS is a byproduct of the industrial livestock industry, and multiple calf fetuses are required to make a single liter of FBS.¹¹³ So, to mass produce cellular meat, manufacturers would need a constant supply of pregnant cows for slaughter. Thus, the result is a Catch-22: in attempting to shrink the industrialized livestock industry by growing meat in the lab, manufacturers demand more livestock to supply the necessary FBS. Alternatives to FBS exist, but the industry will need a push—and perhaps, permission—to switch.¹¹⁴

Another pressing issue addresses which agency is best equipped to regulate the technical lab processes used to cultivate cellular meat. And on the harvesting and marketing side—which includes the question of labeling—which agency has the necessary expertise to effectively and efficiently ensure that consumers are both protected and appropriately informed? Proposed responses to these issues are discussed later in Section III.¹¹⁵ The following Section II summarizes the legal framework governing federal responsibility for food safety.¹¹⁶

II. LEGAL FRAMEWORK

In the United States, federal responsibility for food safety rests primarily with the FDA and the USDA-FSIS.¹¹⁷ Broadly speaking, the FDA has authority to regulate the production and labeling of all food, except meat, eggs, and poultry

111. Santo et al., *supra* note 5, at 13.

112. Carlo E A Jochems et al., *The Use of Fetal Bovine Serum: Ethical or Scientific Problem?*, 30 ALT. LAB ANIMAL 219, 220 (2002).

113. Gerhard Gstraunthaler, Toni Lindl & Jan van der Valk, *A plea to reduce or replace fetal bovine serum in cell culture media*, 65 CYTOTECHNOLOGY 791, 792 (2013).

114. See Jan Van der Valk et al., *Fetal bovine serum (FBS): Past – present – future*, 35 ALTEX – ALTS. TO ANIMAL EXPERIMENTATION 99, 99, 103–11 (2018) (explaining research that is underway on alternatives to the use of FBS for cellular agricultural meat production).

115. See *infra* Section III.

116. See *infra* Section II.

117. RENÉE JOHNSON, CONG. RSCH. SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 1 (2016).

products, which fall under the jurisdiction of the USDA.¹¹⁸ The two authorities share jurisdiction over food additives in meat and poultry.¹¹⁹

A. The United States Department of Agriculture

The USDA draws authority for its food safety operations for meat from the Federal Meat Inspection Act (FMIA), which ensures that the United States' commercial supply of meat and meat products are safe, not adulterated, and properly labeled and packaged.¹²⁰ The major provisions of FMIA include mandatory inspections of livestock before slaughter; mandatory postmortem examinations of carcasses; labeling requirements for meat and meat products; sanitary standards for slaughterhouses and meatpacking establishments; and ongoing inspections of slaughterhouses and meatpacking establishments.¹²¹ Under FMIA, "meat food product" is defined as:

[A]ny 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 . . .¹²²

The USDA-FSIS implements FMIA by inspecting meat and other animal products that move through interstate commerce.¹²³ FSIS inspects the meat to ensure it is not adulterated or misbranded.¹²⁴ Under FMIA, "adulteration" applies to a "carcass, part thereof, [and] meat or meat food product."¹²⁵ A product is adulterated if it meets the following properties: it contains any poisonous or deleterious substance which may render it injurious to health;¹²⁶ it contains any added poisonous or added deleterious substance other than those approved;¹²⁷ it is, in whole or in part, a raw agricultural commodity that contains a pesticide chemical which is declared unsafe;¹²⁸ it contains any food additive which is

118. *Id.* at 4.

119. Post et al., *supra* note 2, at 410.

120. 21 U.S.C. §§ 601–695.

121. *Id.*

122. 21 U.S.C. § 601(j).

123. Sanchez, *supra* note 9.

124. 21 U.S.C. § 610(d).

125. *Id.* § 610.

126. *Id.* § 601(m)(1).

127. *Id.* § 601(m)(2)(A).

128. *Id.* § 601(m)(2)(B).

declared unsafe by the FDA;¹²⁹ it consists in whole or in part of any filthy, putrid, or decomposed substances or is for any other reason unsound, *unhealthful*, *unwholesome*, or otherwise unfit for human food;¹³⁰ and it has been prepared, packed, or held under *insanitary conditions*.¹³¹

B. The Food and Drug Administration

The FDA draws regulatory authority from the Federal Food, Drug, and Cosmetic Act.¹³² With a few exceptions (like food additives), the FDCA authorizes the FDA to regulate food through post-marketing mechanisms such as inspections, testing, and enforcing adulteration and misbranding standards and good manufacturing practices.¹³³ The Center for Food Safety and Applied Nutrition (CFSAN) division within the FDA ensures that the nation's food supply is safe, sanitary, wholesome, and honestly labeled.¹³⁴

FDCA Section 409 requires premarket approval for any food additive.¹³⁵ The use of any unapproved food additive renders the food unsafe and thereby subject to adulteration provisions in FDCA Section 402.¹³⁶ A food additive is any substance that is intentionally added to food, unless the substance is generally recognized as safe (GRAS) for its intended use or is excluded for other reasons.¹³⁷ A substance is GRAS under the condition of its intended use if it meets the following two criteria. First, the use of the substance must meet the same safety standards as a food additive: there must be a reasonable certainty of no harm under the conditions of its intended use.¹³⁸ Second, the use of the substance must meet the general recognition standard: the intended use of the substance in food must be generally recognized as safe by qualified experts based on publicly available scientific information.¹³⁹ Proponents of a substance may

129. *Id.* § 601(m)(2)(C).

130. *Id.* § 601(m)(3) (emphasis added).

131. *Id.* § 601(m)(4) (emphasis added).

132. *What is the difference between the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA regulations, and FDA guidance?*, FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/fda-basics/what-difference-between-federal-food-drug-and-cosmetic-act-fdc-act-fda-regulations-and-fda-guidance> (Mar. 28, 2018).

133. *What We Do at CFSAN*, FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/default.htm> (Sept. 16, 2019).

134. *Id.*

135. *Generally Recognized as Safe (GRAS)*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras> (Sept. 6, 2019).

136. *Determining the Regulatory Status of a Food Ingredient*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/food-ingredients-packaging/determining-regulatory-status-food-ingredient> (Sept. 20, 2018).

137. 21 U.S.C. § 321(s).

138. 21 C.F.R. § 170.30(a) (2016).

139. *Id.*

use a “GRAS panel” to establish that a substance is GRAS.¹⁴⁰ A GRAS panel is “a group of qualified scientific experts who independently evaluate whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in human food or animal food.”¹⁴¹

The FDA also governs food products that are developed using novel tools of biotechnology through its Biotechnology Policy.¹⁴² The policy focuses on food derived from new plant varieties developed by methods of genetic modification.¹⁴³ Under the policy, “the regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components).”¹⁴⁴ The policy explains that while the method by which food is produced or developed may help to understand the safety or nutritional characteristics of the finished food product, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.¹⁴⁵

C. The Current Agency Agreement for Regulating Cellular Meat

As cellular meat emerged, both the USDA and FDA expressed interest in resolving the food safety and regulatory issues arising from the new technology. In June 2018, the FDA issued a statement about cultured food products, referring to the “development of products that are intended to resemble conventional meat, poultry, seafood . . . generally made from cells collected from animals that are multiplied using non-traditional food technologies.”¹⁴⁶ The FDA proceeded to assert regulatory jurisdiction over these products under the FDCA.¹⁴⁷ In response, the USDA emphasized its own responsibility to oversee products marketed as meat, and its willingness to work with the FDA.¹⁴⁸ The FDA held a public meeting to discuss cultured meat, focusing on food safety issues.¹⁴⁹ And

140. Sanchez, *supra* note 9.

141. *Id.*

142. 57 Fed. Reg. 22984, 22984 (May 29, 1992).

143. *Id.*

144. *Id.*

145. *Id.* at 22984–85.

146. Press Release, Scott Gottlieb, FDA Commissioner, Statement from FDA Commissioner Scott Gottlieb, M.D. and FDA Deputy Commissioner Anna Abram on emerging food innovation, “cultured” food products (June 15, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-fda-deputy-commissioner-anna-abram-emerging-food>.

147. *Id.*

148. GREENE & ANGADJIVAND, *supra* note 86.

149. *FDA Announces Public Meeting to Discuss Foods Produced Using Animal Cell Culture Technology*, FOOD & DRUG ADMIN., <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-public-meeting-discuss-foods-produced-using-animal-cell-culture-technology> (June 19, 2018).

months later, the FDA and USDA-FSIS held a joint meeting with stakeholders to discuss animal cell-cultured food technology.¹⁵⁰

Following the joint meeting, in November 2018, the USDA and FDA issued a joint statement on the regulation of cell-cultured food products expressing the agencies' agreement "to oversee cell-cultured food products under a joint regulatory framework."¹⁵¹ The agencies stated that this framework would take advantage of both the "FDA's experience regulating cell-culture technology and living biosystems and the USDA's expertise in regulating livestock and poultry products for human consumption."¹⁵² Furthermore, the agencies asserted that no new federal legislation was necessary, as this framework could be implemented under existing statutory authority.¹⁵³

In March 2019, the USDA and FDA issued a Formal Agreement regarding "the oversight of human food produced using animal cell culture technology, derived from cell lines of USDA-amenable species and required to bear a USDA mark of inspection."¹⁵⁴ The agreement outlined relevant statutory authority and delegated specific responsibilities to the FDA and USDA-FSIS.¹⁵⁵ Under the agreement, the FDA will regulate the early stages of cultured meat production, whereupon oversight will then move to the USDA-FSIS at cell harvest stage.¹⁵⁶ According to the agreement, the agencies will continue to develop a more detailed framework, establish joint principles for labeling and product claims, cooperate in investigating food safety issues for cell-cultured products, and identify possible statutory or regulatory changes required for effective oversight.¹⁵⁷

While this agreement is a starting point, it is not legally binding. The agreement explicitly states that it "does not create enforceable obligations against" the agencies but merely "represents the broad outline of the Parties' present intent to collaborate in areas of mutual interest to HHS-FDA and USDA-FSIS."¹⁵⁸ With no legally binding regulatory structure in place, the threshold issue remains: What regulatory scheme *should* govern cellular meat, consistent with the existing legal framework?

150. 83 Fed. Reg. 46476, 46476 (Sept. 13, 2018).

151. Grossman, *supra* note 7, at 387.

152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.*

158. Post et al., *supra* note 2, at 409.

III. ANALYSIS

The manner in which cellular meat is regulated will be a determining factor in the success of the product. As such, even if the product is successfully produced at scale, consumer acceptance is necessary—and consumer acceptance largely depends on appropriate regulation.¹⁵⁹

The following discussion analyzes, from two perspectives, the functions of the FDA and USDA-FSIS to determine the appropriate federal agency or agencies to regulate cellular meat. While Section III.A considers which agency or agencies are the most appropriate regulators of cellular meat, based on existing statutory and regulatory authority,¹⁶⁰ Section III.B considers which agency or agencies are the most appropriate regulators from a policy perspective.¹⁶¹ Policy should be the deciding factor where there is ambiguity or flexibility in the law.

A. An Argument in Support of Shared Jurisdiction

There is contention among stakeholders on the appropriate scheme for the regulation of cellular meat under the existing legal framework.¹⁶² From these disagreements, three alternative regulatory schemes have emerged: (1) exclusive FDA jurisdiction; (2) exclusive USDA jurisdiction; or (3) shared jurisdiction. The following discussion analyzes the legal arguments in support of each of these competing options, along with an examination of the relative policy pros and cons. Much of the analysis rests on the question of whether cellular meat is in fact “meat,” and if so, whether it is *always* “meat” (from inception), or whether it *becomes* “meat” at a certain point in the production process.

1. USDA’s Arguable Claim to Exclusive Jurisdiction Over the Regulation of Cellular Meat

The USDA has an arguable claim to exclusive jurisdiction over cellular meat, from cell collection to production, labeling, and distribution. As previously explained, the USDA has jurisdiction over “meat food product[s].”¹⁶³ At first blush, it may seem difficult to believe that cultured meat falls within the technical definition of “meat food product” in the FMIA, as arguably, it is not “made wholly or in part from any meat or other portion of the carcass of any cattle.”¹⁶⁴ However, there is a plausible argument that a “carcass” is not necessary, because the definition can potentially be interpreted to include two alternatives: (1) a

159. Grossman, *supra* note 7, at 389.

160. *See infra* Section III.A.

161. *See infra* Section III.B.

162. *See* Grossman, *supra* note 7, at 386 (explaining differing views on which agency should govern cellular meat).

163. 21 U.S.C. § 601(j).

164. *Id.*

product “made wholly or in part from any meat,” or (2) a product “made wholly or in part from ... [a] portion of the carcass of any cattle.”¹⁶⁵ Cultured meat falls within the first alternative since its fundamental character, at the cellular level, is undeniably “meat” at every stage of the cultivation process—from the animal stem cells that start the process through the final product found on grocery shelves.¹⁶⁶

Some argue that other language in the “meat food product” definition supports the USDA’s jurisdiction. The definition excludes products that “historically have not been considered by consumers as products of the meat food industry” and “are not represented as meat food products.”¹⁶⁷ This suggests that a product that consumers *do* perceive as being a product of the meat industry and/or *is* represented as a meat food product arguably falls within the scope of the FMIA.¹⁶⁸ Cellular meat is distinguishable from other foods on the market that mimic the taste and appearance of meat but are plant-based and not marketed as meat, nor perceived to be a product of the meat industry.¹⁶⁹ A plausible argument can be made that cellular meat is a “meat food product” within the meaning of the FMIA, and that the USDA accordingly should have exclusive jurisdiction over all stages of production and distribution.¹⁷⁰

There is an important caveat, however: even if cellular meat products were considered a “meat food product” from inception, the FDA might nevertheless retain jurisdiction to regulate certain ingredients used in the production process as “food additives” under FDCA section 409.¹⁷¹ According to the FDA, “[t]he statutory definition of ‘food additive’ makes clear that it is the intended or expected introduction of a substance into food that makes the substance potentially subject to food additive regulation.”¹⁷² For cellular meat, culture medium and cellular growth factors are added to promote the culturing of cells.¹⁷³ These substances could be considered food additives, as they are substances intentionally added to a food.¹⁷⁴ Accepting this argument would mean that the FDA could require cellular meat producers to submit a food additive petition for the cell culture medium and cellular growth factors, unless they are already-approved additives or GRAS.¹⁷⁵

165. See Sanchez, *supra* note 9 (defining “meat food product” under FMIA).

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.*

171. 21 U.S.C. § 348.

172. Sanchez, *supra* note 9.

173. Shruti Sharma, Sukhcharanjit S. Thind & Amarjeet Kaur, *In vitro meat production system: why and how?*, 52 J. FOOD & SCI. TECH. 7559, 7601 (2015).

174. *Id.*

175. Sanchez, *supra* note 9.

2. FDA's Arguable Claim to Exclusive Jurisdiction Over the Regulation of Cellular Meat

Like the USDA, the FDA also has an arguable competing claim to exclusive jurisdiction over cellular meat. As summarized above, the FDA has broad jurisdiction under the FDAC to govern food, with the exception of “meat food products,” which are regulated by the USDA-FSIS under FMIA. Because cellular meat is an “article . . . used for food or drink for man,”¹⁷⁶ the FDA would have exclusive jurisdiction to govern cellular meat products at all stages of production and distribution to the extent those products do not start as—and never become—“meat food products” governed exclusively by the FMIA.

Several persuasive arguments can be made on why cellular meat is *not* a meat food product under FMIA at any stage of cultivation. First, it may be argued that cellular meat is not “made wholly or in part from any meat or other portion of the carcass,” as a carcass is not involved in any part of the cellular meat process—and the phrase “or *other* portion of” in the definition arguably implies that the term “any meat” means meat “of [a] carcass”—*i.e.*, that the term “meat” is limited to muscle cut from the dead carcass of a once-live animal.¹⁷⁷ Second, it may be argued that cellular meats “historically have not been considered by consumers as products of the meat food industry,” and are thus excluded from the term “meat food product” within the meaning of the FMIA.¹⁷⁸ Third, it may be argued that if cellular meat contains any meat at all, only “a relatively small proportion” is actual animal meat, namely the few original stem cells that came from an animal’s muscle, and is consequently excluded from regulation under the FMIA.¹⁷⁹

If any of these arguments were to prevail, it would not be difficult for the FDA to claim exclusive jurisdiction over cellular meat products, given the agency’s history with food products developed using novel biotechnology.

3. The USDA and FDA Have Reasonable Claims to Shared Jurisdiction Over the Regulation of Cellular Meat

The most legally defensible alternative for the regulation of cellular meat is for the FDA and USDA to share jurisdiction, consistent with the agencies’ March 2019 Agreement. Neither of the arguments outlined above for either *exclusive* USDA jurisdiction or *exclusive* FDA jurisdiction are entirely convincing. The argument for exclusive USDA jurisdiction falls short, as it is difficult to claim that the product is a “meat food product” at the early stages of cell proliferation and differentiation. The argument for exclusive FDA jurisdiction is equally

176. 21 U.S.C. § 321(f).

177. Sanchez, *supra* note 9.

178. *Id.*

179. *Id.*

failable, as it may be difficult to maintain that cellular meat is not a “meat food product” once the cells have proliferated and differentiated to form animal muscle that is materially indistinguishable from traditional agricultural meat.

There is thus a strong legal argument for a joint regulatory scheme, combining the most convincing parts of both arguments for exclusive FDA or exclusive USDA jurisdiction. Under this approach, the FDA would govern the cellular meat cultivation process in its early stages, before the stem cells grow into recognizable “meat”—*i.e.*, differentiated animal muscle. The FDA would regulate the pre-meat product as food “components” under 321(f)(3).¹⁸⁰ For example, the FDA would be responsible for conducting a premarket consultation process to evaluate production materials and processes in manufacturing controls.¹⁸¹ This would include oversight of tissue collection, cell lines, cell banks, and all other components and inputs.¹⁸² Additionally, the FDA would ensure that cellular meat labs are registered, meet FDA requirements for manufacturing, and that cell cultures are safe and not adulterated according to Section 402 of the FDCA.¹⁸³ Lastly, the FDA would oversee proliferation and differentiation of cells up until “harvest,” when the cellular meat components are ready to be processed into recognizable meat products.¹⁸⁴

At the harvest stage, once the cells have proliferated, differentiated, and the product has transformed from “food components” into a “meat food product” under FMIA, oversight would then transfer to the USDA-FSIS.¹⁸⁵ While a carcass is not involved in the process, the definition of “meat food product” under FMIA refers to any product “made wholly or in part from any meat.”¹⁸⁶ Consistent with that definition, the muscle mass—the end product of the cellular meat production process—has the appearance of something that consumers perceive as a product of the meat industry and that is represented as meat food products.¹⁸⁷ USDA-FSIS would therefore have jurisdiction over the cellular meat product and would govern the inspections of processing facilities and product labeling, according to FMIA section 606(a). Additionally, USDA would ensure that harvested muscle cells are eligible to be processed into meat products that

180. See 21 U.S.C. § 321(f) (defining the term “food”).

181. Robert Hibbert & Amaru Sanchez, *Unanswered Questions on FDA-USDA Cell Culture Agreement*, LAW 360 (Apr. 5, 2019, 3:05 PM), <https://www.law360.com/articles/1146763/unanswered-questions-on-fda-usda-cell-culture-agreement> [hereinafter Hibbert & Sanchez II].

182. *Id.*

183. Penn, *supra* note 1, at 387.

184. *Id.*

185. Hibbert & Sanchez II, *supra* note 181.

186. See 21 U.S.C. § 601(j) (defining “meat food product”).

187. *Id.*

bear the USDA mark of inspection.¹⁸⁸ Specifically, the USDA would ensure that the products are “safe, unadulterated, wholesome and properly labeled.”¹⁸⁹

B. Policy Considerations Support Shared Jurisdiction by the FDA and USDA

Policy considerations strongly support a shared jurisdiction regulatory scheme that would allow the FDA and the USDA to take advantage of each agency’s expertise. However, a potential drawback of shared jurisdiction is that it could result in miscommunication and other inefficiencies. Accordingly, it is crucial that the responsibilities of each agency be carefully defined and that effective communication protocols be established and consistently followed.

Arguments supporting USDA involvement include the fact that cellular meat is designed to replicate the properties of traditional agricultural meat, and the USDA has expertise and a long-standing role in governing meat production.¹⁹⁰ USDA inspection of meat producers is robust and well-funded;¹⁹¹ FSIS is required to maintain a continuous, day-to-day presence in meat and poultry production facilities.¹⁹² This type of continuous day to day monitoring is not required for FDA-regulated foods.¹⁹³ Consequently, it is more difficult for the FDA to shut down a facility than the USDA if problems are detected. Effective oversight and enforcement are likely to be key factors in consumer acceptance.

In addition to its regulatory expertise, the mere fact that USDA is involved in the regulation of cellular meat may go a long way in allowing consumers to embrace the product. Consumers who are unwilling to opt for vegetarian food, such as veggie burgers or other plant-based proteins, may be more willing to switch from traditional agricultural meat to cellular meat. A stamp of approval by the USDA that treats cellular meat the same as traditional agricultural meat could be a critical factor for these consumers.

While USDA involvement would be sensible, the agency’s jurisdiction should not be exclusive. The USDA is not accustomed to regulating biotechnologies, and facilities producing cultured meat are very different from traditional slaughterhouses.¹⁹⁴ USDA-FSIS would need to increase its scientific capabilities, tools, expertise, and inspection processes to properly apply the inspection and oversight provisions of FMIA to cultured meat facilities. The

188. Hibbert & Sanchez II, *supra* note 181.

189. See Sanchez, *supra* note 9 (explaining the USDA’s role under FMIA).

190. *Id.*

191. See 21 U.S.C. § 602 (outlining USDA’s inspection responsibilities).

192. USDA, 2021 USDA EXPLANATORY NOTES- FOOD SAFETY AND INSPECTION SERVICE 12 (2021).

193. See George Huang, *FDA Inspection Readiness: What to Expect and How to Prepare*, INTOUCH (Sep. 25, 2018), <https://www.intouch-quality.com/blog/fda-inspection-readiness-what-to-expect-and-how-to-prepare> (noting that routine inspections generally happen every two years).

194. Sanchez, *supra* note 9.

types of facilities that produce cellular meat bear a closer resemblance to food manufacturing sites and laboratories traditionally regulated by FDA than the types of livestock slaughterhouses typically regulated by FSIS.¹⁹⁵ Likewise, the FDA has experience in regulating new food technologies.¹⁹⁶

Additionally, the FDA may be a more neutral regulator of cellular meat. Since the USDA has a long-established regulatory relationship with traditional meat and poultry producers,¹⁹⁷ USDA regulatory decisions could be unfairly influenced by these familiar stakeholders. For example, the United States Cattlemen's Association has already expressed concern about the labeling of cultured meat.¹⁹⁸ The Association supports FSIS labeling authority over cellular meat labeling but insists that the terms "meat" and "beef" should be reserved for "products derived exclusively from the flesh of a bovine animal harvested in the traditional manner."¹⁹⁹ The Association therefore suggested that FSIS develop a meat inspection stamp with a new format and color for cellular meat.²⁰⁰ These and other similar proposals could undermine consumer acceptance of the product.

Careful consideration of the existing legal framework and policy concerns reveals a shared jurisdiction regulatory scheme as the best option, as it would allow both the FDA and the USDA to operate most closely to their conventional roles, taking advantage of each agency's expertise.²⁰¹ The FDA would be able to use its knowledge in biomedical technology to oversee the initial phases of cell-based meat development, while the USDA would be able to use its knowledge in meat production and inspection to make sure the final cell-based meat products are safe and wholesome.

The most significant downside is that shared jurisdiction may result in miscommunication and other inefficiencies, especially at the "harvest" stage when jurisdiction passes from the FDA to the USDA. Under the current Formal Agreement between the two agencies,²⁰² the FDA is responsible for coordinating transfer of oversight and providing necessary information for the USDA to determine whether the cellular meat material is eligible to be processed into meat

195. Alan Sachs & Sarah Kettenmann, *A Burger by Any Other Name: Regulatory Challenges and Opportunities for Cell-Cultured Meat*, 15 SCITECH LAW. 17, 21 (2019).

196. Sanchez, *supra* note 9.

197. Steve Johnson, *The Politics of Meat*, FRONTLINE, <https://www.pbs.org/wgbh/pages/frontline/shows/meat/politics/> (last visited Feb. 25, 2022).

198. Press Release, US Cattlemen's Association, U.S. Cattlemen's Association Responds to Formal Agreement to Regulate Cell-cultured Food Products (Mar. 7, 2019), [https://mailchi.mp/us cattlemen/truth-in-labeling-1818249?e=\[UNIQID\]](https://mailchi.mp/us cattlemen/truth-in-labeling-1818249?e=[UNIQID]).

199. *Id.*

200. *Id.*

201. Sachs & Kettenmann, *supra* note 195, at 20.

202. *See supra* Section III.C.

products.²⁰³ Given the complexity of the process, it would be nearly impossible for the FDA to debrief the USDA on all the background information regarding the cellular meat's production process. Such incomplete communications and transfer from one agency to another may also slow down the oversight process. Still, despite the potential for miscommunication and other related inefficiencies, ultimately the best method to regulate cellular meat is a joint oversight scheme, for the reasons discussed above.

IV. CONCLUSION

How cellular meat is regulated will be a decisive factor in consumer acceptance and in the ultimate success of the product. The strongest argument, from both legal and policy perspectives, is for a shared jurisdiction regulatory scheme that will allow both the FDA and the USDA to take advantage of their respective industry competencies and expertise. The FDA would oversee the biotechnology-heavy initial phases of cellular meat development, when the cells are mere "food components" that have not yet differentiated into a "meat food product." Then once the cells have transformed into a recognizable "meat food product" ready for harvesting, the USDA would oversee processing facilities and product labeling for distribution to consumers.

203. Penn, *supra* note 1, at 387.