Journal of Technology Law & Policy

Volume 24 | Issue 1 Article 1

Regulating The Impending Transformation of the Meat Industry: "Cultured Meat"

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REGULATING THE IMPENDING TRANSFORMATION OF THE MEAT INDUSTRY: "CULTURED MEAT"

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INTRODUCTION

The year is 2022. You and your friend are hungry, so you go down the street to your friend's favorite new burger joint for lunch. You sit down and tell the waiter that you want a burger with cheese, medium rare. Fifteen minutes later, your food comes out. You take a bite. It tastes just like the burgers your dad used to grill—right down to the ridiculous amount of grease and the red, slightly undercooked center. About halfway through your burger, your friend mentions, "Yeah, I like this place because they serve those new burgers grown in labs. It's good for the environment!" You stop chewing and consider spitting it out, but you decide against it, reluctantly swallowing. Grown in a lab, what does that mean? Is this a joke?

Strange as it may sound, this new meat grown in a lab could soon be a reality.[1] It goes by many names, including: "clean meat," "lab-grown meat," "artificial" or "synthetic meat," "in-vitro meat," "cell-based meat," and even "Franken-meat."[2] The American government seems to prefer "cell-cultured" or "cultured meat," so I will use that terminology in this Article.[3] If the "ick factor" demonstrated in the hypothetical above can be overcome, the benefits of cell-cultured meat could be pretty incredible.[4] However, with those potential benefits come potential risks,

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1. *See* discussion *infra* Section I.B para. 1.

2. *See, e.g.*, U.S. FOOD & DRUG ADMIN., *Foods Produced Using Animal Cell Culture Technology*, Docket No. FDA-2018-N-2155, at 92, 151 (July 12, 2018), https://www.fda.gov/media/115122/download [hereinafter *FDA Transcript*] (comparing the popularity of these names for cell-cultured meat); Alan Boyle, *It's (Not) Alive! Franken-Meat Lurches from the Lab to the Frying Pan*, NBC NEWS (Aug. 4, 2013, 5:55 PM), https://www.nbcnews.com/technolog/its-not-alive-franken-meat-lurches-lab-frying-pan-6C1083 5458.

3. JOEL L. GREENE & SAHAR ANGADJIVAND, CONG. RESEARCH SERV., IF10947, REGULATION OF CELL-CULTURED MEAT 1 (2018) [hereinafter CRS ON CULTURED MEAT]; s*ee infra* Section IV.B for a discussion on why to prefer "cultured" as a legal matter, as well; s*ee, e.g.*, *FDA Transcript*, *supra* note 2, at 91–92. *See infra* Section IV.B for a discussion on why to prefer "cultured" as a legal matter, as well.

4. *See* Charlotte Hawks, *How Close are We to a Hamburger Grown in a Lab?*, CNN (Mar. 8, 2018, 2:23 PM), https://www.cnn.com/2018/03/01/health/clean-in-vitro-meat-food/index.html (coining the term "ick factor" to describe the obstacle of people's general disgust with the idea of cultured meat); discussion *infra* Section I.B.2.

including unknown health problems, both from foodborne illness and long-term health risks.[5] Due to these potential benefits and risks, it is necessary to determine: (1) how this new technology will be regulated, and (2) who will regulate it.

Although the United States Department of Agriculture (USDA)'s Food Safety and Inspection Service (FSIS) typically regulates "meat," the Federal Drug Administration (FDA) claims that it is better prepared to regulate this new technology given its experience regulating similar biotechnologies.[6] Thus, both the USDA and FDA currently claim to have jurisdiction over cell-cultured meat.[7]

So, why does it matter which agency regulates cell-cultured meat? It matters because each agency has different principles that govern how it regulates food safety.[8] Generally, the USDA regulates the specific procedures used to prepare the food to ensure its safety; the FDA, however, is mainly concerned with the safety of the final product and only considers the processes used to identify potential safety risks when evaluating the final product.[9] Accordingly, meat lobbyists, such as the United States Cattlemen's Association (USCA), generally support the USDA's sole jurisdiction over cell-cultured meat and clear labeling practices, which distinguish cultured meat from "real meat."[10] On the other hand, environmentalists, animal rights activists, and other supporters of cell-cultured meat generally support placing it under the FDA's sole jurisdiction, which would afford more lax labeling requirements.[11]

This issue should not be decided based on a particular interest group's desires, but rather upon a weighing of the potential benefits of a quick deployment of the new technology against the potential risks to human health at each stage of production. Thus, I argue that, because the FDA is better prepared to regulate new technologies, and has some experience in the regulation of meat, it should hold sole jurisdiction of regulation up to the point that cell-cultured meat becomes "meat," in the traditional sense, at harvest. However, because the USDA is better prepared to regulate traditional meat and its vulnerability to foodborne illness, the USDA should regulate cell-cultured meat as it would other forms of meat from that point on. However, the FDA should have sole jurisdiction over cell-

5. *See* discussion *infra* Section I.B.2.
6. *See* discussion *infra* Section I.C.
7. *See* discussion *infra* Section I.C.
8. *See* discussion *infra* Section I.A.1.
9. *See* discussion *infra* Section I.A.1.
10. *See* discussion *infra* Section I.B.3.
11. *See* discussion *infra* Section I.B.3.

cultured meats that already fall under its purview, including wild game and non-catfish seafood.

In Part I of this Article, I lay a background for the current regulatory framework of safety and labeling applied by the USDA and FDA, the current understandings and hopes concerning cultured meat, and the current debate regarding the future regulation of cultured meat. In Part II, I argue that both the USDA and FDA have statutory authority to claim jurisdiction over cultured meat. In Part III, I argue that the framework proposed by the two agencies properly grants the FDA jurisdiction over pre-harvest safety of cell-cultured meats and grants the USDA jurisdiction over post-harvest safety of meats that would normally fall under its jurisdiction. However, in Part IV, I argue that the agencies should also split jurisdiction of labeling in a way that allows the FDA to determine whether cell-cultured meat fits within a newly defined statement of identity and allows the USDA to regulate its labeling. Finally, I conclude that, although the USDA and FDA's proposed framework for sharing jurisdiction is the best possible framework to ensure food safety and is properly based in the law, it improperly gives sole power over labeling cell-cultured meat to the USDA.

I. BACKGROUND

A. *The Current Framework of Food Regulation*

There are currently two agencies that regulate food safety for human consumption, the USDA and FDA. Generally, the USDA regulates most red meats, poultry, and the processing and grading of eggs, while the FDA regulates non-meat food, dietary supplements, seafood, wild game, and eggs in the shell.[12]

1. Sources of Agency Jurisdiction

The FDA and USDA derive their jurisdiction over particular foods from multiple statutes. The USDA's FSIS implements and enforces the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA), which collectively grant the USDA general jurisdiction over red meat, poultry, and eggs.[13] The USDA bases its operations on the principles of "Hazard Analysis and Critical Control Points" (HACCPs).[14] HACCPs analyze the process of

12. NEAL D. FORTIN, FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE 14 (2d ed. 2017).

13. 21 U.S.C. §§ 451–72, 601–95, 1031–56 (2018); CRS ON CULTURED MEAT, *supra* note 3.

14. *Id.*

producing various foods and develop methods intended to mitigate the risks to food safety that such products produce.[15]

The FDA, in contrast, implements and enforces the Federal Food, Drug, and Cosmetic Act (FFDCA), Public Health Service Act (PHSA), and Fair Packaging and Labeling Act (FPLA).[16] Together these laws grant the FDA jurisdiction over many different aspects of food production, including the regulation of "food."[17] The FDA evaluates foods based on various principles, including the "Generally Regarded as Safe" (GRAS) Principle, but generally focuses on the safety of the final product rather than the method used to produce it to determine safety.[18] However, the FDA and USDA do share jurisdiction over certain foods, such as catfish.[19] When this occurs, the two agencies create a "Memorandum of Understanding" (MOU) to facilitate regulation.[20]

2. Jurisdiction of "Meat" Regulation

The USDA is generally responsible for the regulation of meat, but this is not always true.[21] For instance, the USDA exclusively regulates "the slaughter and processing of meat animals."[22] However, because the FDA has jurisdiction over "food additives," the agencies share jurisdiction over the food additives contained in meat.[23] The FDA also has jurisdiction over multi-ingredient products containing "3% or less raw meat."[24] Additionally, the FDA exclusively regulates wild game and all seafood, except catfish.[25]

3. Regulation of Statements of Identity in Labeling

Both the USDA and FDA enforce prohibitions on "misbranded" foods.[26] A food is "misbranded" if one of several conditions is met, including, "[i]f it purports to be–or is represented as a food for which a

15. *Id.*

16. 21 U.S.C. §§ 301–99h (2018); 42 U.S.C. §§ 201–300mm-61 (2018).

17. 21 U.S.C. § 393 (b)(2)(A) (2018); FORTIN, *supra* note 12, at 17.

18. FORTIN, *supra* note 12, at 220–24, 313 (discussing the GRAS principle and its application).

19. CRS ON CULTURED MEAT, *supra* note 3.

20. *Id.*

21. FORTIN, *supra* note 12, at 23.

22. *Id.*

23. *Id.*

24. *Id.*

25. CRS ON CULTURED MEAT, *supra* note 3.

26. *See* 21 U.S.C. § 331 (2018) (FDA regulation of misbranded foods); 21 U.S.C. § 458 (2018) (USDA regulation of misbranded poultry); 21 U.S.C. § 610 (2018) (USDA regulation of misbranded meats); 21 U.S.C. § 1037 (2018) (USDA regulation of misbranded eggs).

definition and standard of identity has been prescribed."[27] Foods are required to show in prominent lettering on their labels a "statement of identity" which correctly represents what they are.[28] Such identifying language has been the focus of various court cases in which parties argued that almond, coconut, and soy "milk" are misbranded because they purport to be "milk," which has its own standard of identity, with little success.[29]

4. FDA Regulation of Emerging Biotechnologies

The FDA is largely responsible for the regulation of emerging food technologies, including genetically modified organisms (GMOs), genetically engineered animals, and cloning.[30] The FDA also has some experience in the use of other cell-cultured technologies, including: cell-cultures utilized in medical applications (such as insulin), algae cultured to produce oils, bacteria cultures found in yogurt, cultured yeasts used as additives in bread products, and common protein additives such as mycoproteins.[31]

B. *Cultured Meat*

Cell-cultured meat, or cultured meat, is an emerging technology that may challenge the current regulatory framework. Although the first burger made with cultured meat was sold at the outrageous price of $300,000 in 2013, the technology has been rapidly developing to produce cultured meat more efficiently so that it is readily available, with the price now set around $600 per buyer.[32] Some estimates show that cultured meat will be available by 2021 in niche markets and available on an industrial scale by 2024 for as low as $1 for a typical hamburger patty.[33] In the wake of major companies such as Tyson announcing major investments, "2019 is shaping up to be the year that startups and big businesses invest more

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27. 21 U.S.C. § 343 (g) (2018).

28. § 343 (f)–(g).

29. *See, e.g.*, Ang v. Whitewave Foods Co., No. 13-CV-1953, 2013 WL 6492353, at *4 (N.D. Cal. Dec. 10, 2013) (unreported) (dismissing with prejudice the class action against soy milk, almond milk, and coconut milk producers because the products "clearly convey the basic nature and content of the beverages, while clearly distinguishing them from milk that is derived from dairy cows," and it is "simply implausible that a reasonable consumer would mistake" such a product for cow's milk).

30. FORTIN, *supra* note 12, at 285–86, 291, 315.

31. *FDA Transcript*, *supra* note 2, at 16, 44, 46, 47.

32. *See* G. Owen Schaefer, *Lab-Grown Meat*, SCIENTIFIC AMERICAN (Sept. 14, 2018), https://www.scientificamerican.com/article/lab-grown-meat/.

33. CBS NEWS, *Lab-Grown Meat Could be in Restaurants by 2021* (July 17, 2018, 10:14 PM), https://www.cbsnews.com/news/mosa-meat-lab-grown-meat-could-be-restaurants-by-2021.

in the alternative protein space."[34] With this in mind, regulations must be established quickly to ensure that this promising technology is safely, but quickly implemented.

1. Production of Cell-Cultured Meat

Cell-cultured meat is created by, first, taking a muscle sample from an animal.[35] From that sample, stem cells are taken and placed in a bio-reactor, where they are fed a nutrient medium and allowed to multiply exponentially.[36] This nutrient medium may include water, amino acids, vitamins, sugars, lipids, minerals, protein factors, and hormones, which enable the cells to grow naturally as they would in a living animal.[37] From one original cow's muscle sample, an estimated 80,000 quarter-pound burgers could be created.[38] Meanwhile, the cells' environment is controlled within a unique bioreactor so that the feed supply, temperature, pH, and oxygen levels can be controlled to efficiently form tissue.[39] After the cells have multiplied and formed tissue, the cell medium is drained, and the tissue is harvested, rinsed, and analyzed for quality to ensure that there are no impurities.[40]

2. Potential Impacts of Cultured Meat Development

Cultured meat has been heralded by various groups as a solution to many current problems. Perhaps most notably, environmentalists view cultured meat as a possible solution to the significant environmental impacts associated with meat production.[41] It is well-established that meat production, and especially beef production, has severely harmful effects on our environment due to its exorbitant energy, land, and water usage, as well as CO2 greenhouse gas (GHG) emissions (which

34. Nathan Owens, *Tyson Plans Own Plant-Based Foods*, ARK. DEMOCRAT GAZETTE (Feb. 9, 2019, 4:30 AM), https://www.arkansasonline.com/news/2019/feb/09/tyson-plans-own-plant-based-foods-20190/ (reporting on Tyson's announcement earlier that week that Tyson will be launching their own alternative protein source that could be on shelves by the end of 2019, although Tyson has not yet indicated whether this protein source will be cell-cultured or a plant-based protein product).

35. Schaefer, *supra* note 32.

36. *See FDA Transcript*, *supra* note 2, at 96–97.

37. *Id.* at 96.

38. Schaefer, *supra* note 32.

39. *FDA Transcript*, *supra* note 2, at 97.

40. *Id.*

41. *See, e.g.*, Bahar Gholipour, *Lab-Grown Meat May Save a Lot More than Farm Animals' Lives*, NBC NEWS (Apr. 6, 2017, 1:34 PM), https://www.nbcnews.com/mach/innovation/lab-grown-meat-may-save-lot-more-farm-animals-lives-n743091.

contribute to climate change).[42] In one speculative, independent study, scientists found that cultured meat "involves approximately 7-45% lower energy use . . . , 78-96% lower GHG emissions, 99% lower land use, and 82-96% lower water use depending on the product compared."[43] Although this study produced impressive results, it is widely criticized due to its high degree of speculation.[44] While more studies are likely necessary to confirm the study's results based on new information about what methods producers actually use as the technology develops, if even remotely true, these projections are impressive.

Animal rights activists additionally hope that cultured meat can function as a solution to animal abuse issues commonly found in factory farms.[45] Although, in its current state, the production of cultured meat requires the slaughtering of animals for the gathering of base cells, cultured meat offers a far more efficient process, drastically reducing the number of animals slaughtered for meat by unknown numbers.[46] Some animal rights activists hold out hope that initial tissue samples will eventually be taken from live animals via biopsy, eliminating the need to slaughter animals altogether.[47]

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42. *See, e.g.*, FAO, TACKLING CLIMATE CHANGE THROUGH LIVESTOCK: A GLOBAL ASSESSMENT OF EMISSIONS AND MITIGATION OPPORTUNITIES (2013), http://www.fao.org/3/a-i3437e.pdf (tracking emissions from worldwide production of various kinds of livestock); Bryan Walsh, *The Triple Whopper Environmental Impact of Global Meat Production*, TIME (Dec. 16, 2013), http://science.time.com/2013/12/16/the-triple-whopper-environmental-impact-of-global-meat-production/ (examining the impact of livestock production on land, water, and emissions); CENTER FOR SUSTAINABLE SYSTEMS, PUB. NO. CSS09-05, CARBON FOOTPRINT FACTSHEET 1 (Aug. 2018), http://css.umich.edu/sites/default/files/Carbon_Footprint_Factsheet_CSS09-05_e2018_0.pdf (comparing the impact of livestock production on emissions against other sources of food and other industries).

43. Hanna L. Tuomisto & M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, ENVTL. SCI. TECH., 6117, 6117 (2011), https://pubs.acs.org/doi/pdf/10.1021/es200130u.

44. *See, e.g.*, Isha Datar, *Environmental Impacts of Cultured Meat*, NEW HARVEST (July 22, 2014), https://www.new-harvest.org/environmental_impacts_of_cultured_meat (noting criticisms of the study as being based on unproven assumptions about how cultured meat could be grown).

45. *See, e.g.*, Jacy Reese, *Is "Clean Meat" the Solution to Industrial Animal Farming?*, GEO. J. INT'L AFF. (June 25, 2018), https://www.georgetownjournalofinternationalaffairs.org/online-edition/2018/6/24/is-clean-meat-the-solution-to-industrial-animal-farming; *see also* PETA, *PETA's 'In Vitro' Chicken Contest*, https://www.peta.org/features/vitro-meat-contest/ (last updated Mar. 4, 2014) (detailing two contests for the first companies to create cell-cultured beef and chicken, respectively, without slaughtering any animals).

46. *See* Schaefer, *supra* note 32 and accompanying text.

47. *See, e.g.*, *Cultured Meat; Manufacturing of Meat Products Through "Tissue-Engineering" Technology*, FUTURE FOOD, https://www.futurefood.org/in-vitro-meat/index_en.php (last visited Mar. 1, 2019); *see also FDA Transcript*, *supra* note 2, at 167.

Cultured meat has potential positive and negative implications for human health, as well. For instance, cultured meat could be enhanced with beneficial additives, such as vitamin B12.[48] Further, harmful saturated fats could be replaced with healthier omega-3 fatty acids, which have shown promise in treating and preventing various diseases, but the main source of which is disappearing.[49] Cultured meat will most likely be free of the pharmaceutical residues found in some "traditional meat," such as pesticides and growth hormones, but there is some uncertainty as to whether the final product will contain antibiotic residues specifically.[50] Because it is grown in a sterile lab environment, cultured meat may have less of the harmful bacteria responsible for foodborne illness, resulting in considerable health and economic benefits.[51] However, some have cast doubt on the extent to which foodborne illness would actually be reduced, as there is still potential for contamination after harvest.[52] Further, some experts have expressed concerns that the process for creating the cultured meat will create new hazards, some of which may not be discovered until long-term effects have taken hold of consumers.[53]

In addition to the above significant, potential environmental, moral, and health impacts, advancement in cultured meat technology has some less obvious potential consequences. For instance, cultured meat could drastically reduce the cost of kosher meat in the future.[54] As the technology advances, cultured meat could replicate the meats and parts of more exotic animals and flood the markets, expanding our diets and

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

49. *Id.*; *see also* Karen Wright & Susan Kruglinski, *I'll Have My Burger Petri-Dish Bred, with Extra Omega-3*, DISCOVER (Sept. 22, 2008), http://discovermagazine.com/2008/oct/22-ill-have-my-burger-petri-dish-bred.

50. Zaraska, *supra* note 48. It should be noted here that the meat industry generally denies that residues from antibiotics and other drugs are in meat; however, a recent study from Consumer Reports found traces of ketamine, phenylbutazone, chloramphenicol (an antibiotic), and other banned or severely restricted drugs in the U.S. meat supply. *See* Rachel Rabkin Peachman, *Are Banned Drugs in Your Meat?*, CONSUMER REPORTS, https://www.consumerreports.org/food-safety/are-banned-drugs-in-your-meat/ (last updated Nov. 27, 2018).

51. *See* Andy Weisbecker, *Food Illness Costs Substantial, Significant*, FOOD SAFETY NEWS (Dec. 8, 2009), https://www.foodsafetynews.com/2009/12/food-illness-costs-substantial-significant/.

52. *See, e.g.*, Zaraska, *supra* note 48.

53. *See, e.g.*, Markham Heid, *You Asked: Should I Be Nervous About Lab-Grown Meat?*, TIME (Sept. 14, 2016), http://time.com/4490128/artificial-meat-protein/.

54. Elaine Watson, *Orthodox Union: Cell Cultured Meat Could Dramatically Lower the Cost of Kosher Meat in the Future*, FOODNAVIGATOR-USA (Aug. 22, 2018), https://www.foodnavigator-usa.com/Article/2018/08/22/Orthodox-Union-Cell-cultured-meat-could-dramatically-lower-the-cost-of-kosher-meat-in-future.

eliminating the incentive of poaching.[55] Eventually, cultured meat may be even more cost efficient than conventional meat, and would therefore constitute one low-cost way to help abate world hunger.[56] The extent of impacts with this technology is unknown, but promising.

3. Competing Interests in Regulation

Although there are many groups that support cultured meat's quick movement to markets, there are also groups that oppose it. The groups interested in quickly moving the technology to market include environmentalists, animal rights activists, and health scientists.[57] These groups typically favor FDA regulation of cultured meat, which would focus more on the safety of the final product rather than its methods.[58]

However, ranchers and the farmers who produce their feed stand to lose a great deal if cultured meat becomes popular. Thus, ranching and farming interest groups argue for stricter regulations that would, as they see it, allow for fair competition.[59] Further, some groups, such as naturalists, are wary of long-term health detriments stemming from cultured meat's "unnaturalness."[60] These groups generally favor USDA regulation of the processes used in the creation of cultured meat as well as clear product labeling, allowing consumers to make an informed choice on potential unknown detriments of cultured meat consumption.[61]

In light of these competing interests, the questions of who will regulate cell-cultured meat and how they will regulate it have quickly become a hot topic.[62]

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55. JAMIE HOLLYWOOD & MADSEN PIRIE, ADAM SMITH INST., DON'T HAVE A COW, MAN: THE PROSPECTS FOR LAB GROWN MEAT 9 (Aug. 30, 2018), https://static1.squarespace.com/static/56eddde762cd9413e151ac92/t/5b865367575d1f9926d24550/1535529836180/Lab+Grown+Meat+.pdf.

56. *See* CBS NEWS, *supra* note 33.

57. *See supra* Section I.B.2.

58. *See, e.g.*, *FDA Transcript*, *supra* note 2, at 93 (demonstrating that Memphis Meats believes that the current FDA framework should be applied to cultured meats).

59. *See, e.g.*, Leanna Garfield, *There's a Growing Battle Between Fake Meat Startups and Big Beef, and Neither Side is Backing Down*, BUS. INSIDER (June 10, 2018, 10:06 AM), https://www.businessinsider.com/beef-companies-file-petition-against-lab-grown-meat-startups-2018-2; *FDA Transcript*, *supra* note 2, at 200–01.

60. *See* Christopher Bryant & Julie Barnett, *Consumer Acceptance of Cultured Meat: A Systematic Review*, 143 MEAT SCI. 8, 12 (2018) (observing that cell-cultured meat's perceived "unnaturalness" causes some to claim that it is "dangerous to consume," "inherently unethical," or harmful to the environment).

61. *See, e.g.*, Garfield, *supra* note 59 (describing approaches of the traditional meat producer's interest groups in this issue).

62. *See, e.g.*, Helena Bottemiller Evich, *Welcome to the Turf Battle over Lab-Grown Meat*, POLITICO (June 15, 2018, 6:12 PM), https://www.politico.com/story/2018/06/15/lab-grown-meat-feds-turf-battle-629774.

C. *Shifting Thoughts on the Regulation of Cultured Meat*

Until very recently, legal academics generally believed that the FDA would hold sole jurisdiction over cell-cultured meat because the FDA's current regulatory framework was considered best suited to the task.[63]

This assumption was thrown into chaos in April 2018, when "USDA Secretary Perdue, in response to questions on cell-cultured meat, stated that meat and poultry are under the sole purview of the USDA, and any product labeled as meat would be under USDA purview."[64] However, in June 2018 "FDA Commissioner Gottlieb issued a statement on cell-cultured meat announcing that under the FFDCA, the FDA has oversight for cell-cultured meat" additionally announcing that the FDA would hold a public meeting on the regulation of cell-cultured meat.[65] In response, a USDA spokesperson affirmed the USDA's position that the USDA had sole jurisdiction over cell-cultured meat, but stated that the USDA was open to working with the FDA.[66]

In the absence of central authority, this "turf standoff" created significant confusion and attracted the attention of the House Appropriations Committee, which took the position that the USDA has sole jurisdiction over cell-cultured meat.[67] Despite the involvement of the House Appropriations Committee, the FDA moved forward and held its first public meeting in July 2018; the meeting detailed how cell-cultured technology might fit into its existing regulatory framework by comparing it to technology that the FDA already regulates.[68]

However, in September 2018, the USDA and FDA announced that they would hold a joint public meeting in October "to discuss the potential hazards, oversight considerations, and labeling of cell-cultured food products derived from livestock and poultry tissue."[69] This meeting arose in response to the USCA's publication of a petition requesting: (1) that USDA's FSIS be granted sole jurisdiction over cell-cultured meat, and (2) that companies be prevented from labeling cell-cultured meat as "meat" or "beef."[70] Although neither the USDA nor the FDA ceded

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63. *See, e.g.*, Zachary Schneider, *In Vitro Meat: Space Travel, Cannibalism, and Federal Regulation*, 50 HOUS. L. REV. 991, 1014–15 (2013).

64. CRS ON CULTURED MEAT, *supra* note 3, at 2.

65. *Id.*

66. *Id.*

67. Evich, *supra* note 62; CRS ON CULTURED MEAT, *supra* note 3, at 2.

68. *FDA Transcript*, *supra* note 2, at 32–52.

69. Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry, 83 Fed. Reg. 46,476, 46,476 (Sept. 13, 2018), https://www.govinfo.gov/content/pkg/FR-2018-09-13/pdf/2018-19907.pdf.

70. *Id.* at 46,477. This petition attracted a great deal of attention, receiving over 6,100 comments to the USDA.

jurisdiction of any particular aspect of regulation during the meeting, the agencies agreed that they both should have a role in the regulation of cell-cultured meat.[71]

Amid speculation of possible legislation, the USDA and the FDA released a joint statement in November 2018 further clarifying their individual roles (2018 joint statement).[72] According to the statement, the FDA will "oversee[] cell collection, cell banks, and cell growth and differentiation," while the USDA will "oversee the production and labeling of food products derived from the cells of livestock and poultry."[73] Under this framework, "[a] transition from FDA to USDA oversight will occur during the cell harvest stage."[74] The agencies made clear with this statement that they did not want Congress to intervene via its Farm Bill or any other legislation: "[b]ecause our agencies have the statutory authority necessary to appropriately regulate cell-cultured food products derived from livestock and poultry the Administration does not believe that legislation on this topic is necessary."[75] Despite this clear message, speculation remains that Congress may intervene and give USDA sole jurisdiction.[76]

Finally, on March 7, 2019, the FDA and USDA released a joint statement announcing their MOU on their joint regulation of cultured meat.[77] This MOU further details how the joint regulation will occur.[78]

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71. *See, e.g.*, U.S. DEP'T OF AGRIC. & U.S. FOOD & DRUG ADMIN, DOCKET NO. FSIS-2018-0036, USDA AND FDA JOINT PUBLIC MEETING ON THE USE OF CELL CULTURE TECHNOLOGY TO DEVELOP PRODUCTS DERIVED FROM LIVESTOCK AND POULTRY, DAY 2 MORNING SESSION, 7 (Oct. 23–24, 2018) [hereinafter *Joint Transcript*], https://www.fsis.usda.gov/wps/wcm/connect/42c8b917-8c01-459d-8aa3-51e0b67ae84a/transcript-cellular-agriculture-day1-morning-102318.pdf?MOD=AJPERES.

72. U.S. DEP'T OF AGRIC., RELEASE NO. 0248.18, STATEMENT FROM USDA SECRETARY PERDUE AND FDA COMMISSIONER GOTTLIEB ON THE REGULATION OF CELL-CULTURED FOOD PRODUCTS FROM CELL LINES OF LIVESTOCK AND POULTRY (2018), https://www.usda.gov/media/press-releases/2018/11/16/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb [hereinafter USDA AND FDA FIRST STATEMENT ON REGULATION].

73. *Id.*

74. *Id.*

75. *Id.*

76. *See, e.g.*, Liz Crampton, *Cell-Based Meat Issue Could Still be Settled on the Hill*, POLITICO (Nov. 20, 2018, 10:00 AM), https://www.politico.com/newsletters/morning-agriculture/2018/11/20/cell-based-meat-issue-could-still-be-settled-on-the-hill-422882.

77. U.S. DEP'T OF AGRIC., RELEASE NO. 0027.19, USDA AND FDA ANNOUNCE A FORMAL AGREEMENT TO REGULATE CELL-CULTURED FOOD PRODUCTS FROM CELL LINES OF LIVESTOCK AND POULTRY (2019), https://www.usda.gov/media/press-releases/2019/03/07/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food.

78. *See* U.S. DEP'T OF AGRIC. & U.S. FOOD &. DRUG ADMIN., FORMAL AGREEMENT BETWEEN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG

Under the MOU, the FDA will "conduct premarket consultation processes," including "oversight of collection, cell lines and banks, and all components and inputs" and, "[a]t harvest, . . . provid[e] information necessary for USDA to determine whether harvested cells are eligible to be processed into meat or poultry products that bear the USDA mark of inspection."[79] The USDA will then "[c]onduct inspection in establishments where cells cultured from livestock and poultry subject to the FMIA and PPIA are harvested, processed, packaged or labeled" and "[r]equire that the labeling of human food products derived from the cultured cells of livestock and poultry be preapproved and then verified through inspection."[80]

II. STATUTORY AUTHORITY FOR REGULATION

Prior to evaluating this proposed framework of joint jurisdiction, we must first ask, is it legal? That is, do both the FDA and USDA have power under current laws to regulate what they propose to regulate? The statutory basis for both the USDA and FDA's authority to regulate cell-cultured meat is debatable, and the lack of clarity of what cell-cultured meat will look like does not help this issue; ultimately, however, both agencies will likely have the authority to regulate cell-cultured meat in at least some fashion.

As an initial matter, the FDA's sole power to regulate specific forms of traditional meat should extend to any cultured meat forms of those meats. Although no such division was explicitly made in the 2018 joint statement, the title of the statement indicates that it is meant to apply only to "Food Products from Cell Lines of Livestock and Poultry."[81] The FDA's sole power to regulate any cultured meat that falls into one of these categories should be clear as the USDA has no basis for regulating these categories under the current statutory and administrative framework. Thus, the FDA will have the sole power to regulate cell-cultured meat derived from wild game and all seafood except catfish, and any multi-ingredient products containing "3% or less raw [cultured] meat."[82] The remainder of this section thus focuses on each agency's authority to regulate cell-cultured meat that does not fall under one of these categories.

ADMINISTRATION AND U.S. DEPARTMENT OF AGRICULTURE OFFICE OF FOOD SAFETY 2–4 (2019) [hereinafter USDA AND FDA CULTURED MEAT MOU], https://www.fsis.usda.gov/wps/wcm/connect/0d2d644a-9a65-43c6-944f-ea598aacdec1/Formal-Agreement-FSIS-FDA.pdf?MOD=AJPERES.

79. *Id.* at 2.

80. *Id.* at 3.

81. *See* USDA AND FDA FIRST STATEMENT ON REGULATION, *supra* note 72.

82. *See* discussion *supra* Section I.A.2.

A. *USDA Statutory Authority*

The USDA's regulation of meat relies on two parallel statutes providing for the regulation of both poultry and traditional red meats.[83] If cell-cultured meat is a "meat food product," it falls under USDA jurisdiction to regulate per the FMIA.[84] Therefore, arguments for USDA's jurisdiction over cell-cultured red meats rely on the definition of "meat food product," which is composed of three elements.

First, a "meat food product" only applies to products "capable of use as human food which [are] made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats."[85] In its current form, cell-cultured meat likely meets this element because the initial sample used in the culture is taken from the legs of once-living cattle, sheep, swine, or goats.[86] However, groups are working to eliminate the need for a living animal to be slaughtered at all by acquiring initial tissue samples via biopsy from live animals.[87] Arguably, if this alternative process is successful, the USDA may lack jurisdiction to regulate any product derived from the process.

Further, even if taken from a dead animal, it is not totally clear that the tissue sample would constitute a "carcass." Interestingly, "carcass" does not seem to have a definition under the statute. Applying the normal meaning of the word, "carcass" would usually imply that the subject is dead, but the tissue sample itself when taken from the animal is very much alive—it must be alive for the cells to propagate. Thus, cultured meat producers could argue that the USDA does not have proper authority to regulate cultured meat on these grounds.

Second, a product that would otherwise be a "meat food product" *may* be "exempted from definition as a meat food product by the Secretary" *if* it "contain[s] meat or other portions of such carcasses only in a relatively small proportion."[88] The portion of the actual animal carcass used in cell-cultured meat is clearly small in proportion to the amount of meat it creates, but the FDA and USDA's 2018 joint statement shows that the

83. *See* 21 U.S.C. §§ 451–72, 601–95, 1031–56 (2018).

84. *See* 21 U.S.C. § 621 (2018) ("The Secretary shall appoint from time to time inspectors to make examination and inspection of all amenable species, inspection of which is hereby provided for, and of all carcasses and parts thereof, and of all meats and meat food products thereof, and of the sanitary conditions of all establishments in which such meat and meat food products hereinbefore described are prepared.").

85. 21 U.S.C. § 601(j) (2018).

86. *See supra* text accompanying note 58.

87. *See supra* notes 56–58 and accompanying text.

88. 21 U.S.C. § 601(j).

USDA Secretary has no current plans to except cell-cultured meat on this basis.[89] Therefore, this second element is also met.

Third, a product that would otherwise be a "meat food product" also *may* be "exempted from definition as a meat food product by the Secretary" *if* it has not "historically . . . been considered by consumers as [a] product[] of the meat food industry."[90] Again, there is certainly an argument that cell-cultured meat should be exempted because consumers may not consider cell-cultured meat to be a "meat food product," but the USDA has clearly indicated that they will not exclude cell-cultured meat from its authority in total in the near future, and the element is met.[91]

Thus, the USDA likely holds jurisdiction under the FMIA to regulate cell-cultured meat in its current form when derived from traditional red meats, meaning that derived from cattle, sheep, swine, and goats. Further, in the PPIA, equivalent language is used to give the USDA jurisdiction over "poultry product[s]" under the same circumstances (replacing "cattle, sheep, swine, and goats" in the FMIA with "poultry" and keeping the language otherwise the same).[92] Thus, the same arguments applied above to the regulation of "meat food product[s]" will apply to "poultry product[s]," as well.

Ultimately, the USDA likely holds jurisdiction under the FMIA and PPIA to regulate cell-cultured meats derived from traditional red meats and poultry, although this jurisdiction is subject to a shift to plant-based cell-cultured meats, to the uncertain definition of "carcass," and to exception by the USDA Secretary. Additionally, cell-cultured meats that lie outside the limits of USDA regulation in their traditional form, such as seafood and wild game, must also lie outside the limits of USDA regulation in their cell-cultured form, as the USDA does not have any statutory authority to claim jurisdiction in such cases.

B. *FDA Statutory Authority*

The FDA's source of authority to regulate cell-cultured meat is harder to pin down. The FDA has the broad authority to regulate "food," including "articles used for food or drink for man or other animals . . . [and] articles used for components of any such article."[93]

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89. *See supra* notes 49, 84–92 and accompanying text.

90. 21 U.S.C. § 601(j).

91. *See supra* note 86 and accompanying text.

92. 21 U.S.C. § 453(f) (2018) ("The term 'poultry product' means any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by the Secretary.").

93. 21 U.S.C. § 321(f) (2018).

However, the FFDCA expressly exempts those foods which qualify as "[m]eats and meat food products" under the FMIA, and the PPIA further exempts "[p]oultry and poultry products."[94] Therefore, if the USDA has jurisdiction under the FMIA or PPIA to regulate cell-cultured meat, the FDA will not have jurisdiction unless it is established under a separate provision in the future.

While some current laws may seem to provide a basis for FDA authority to regulate cell-cultured meat, most prove inapplicable. The FDA's authority to regulate cannot come from the Cloned Food Labeling Act (CFLA), as the CFLA only applies to products derived from once living, cloned animals and their progeny.[95] Some authorities claim that the FDA's authority also cannot come from New Animal Drug Application (NADA) requirements because scientists have not yet begun altering the DNA of animal tissue samples so as to create a genetically modified meat, though this may be a possibility in the future.[96]

There is significant disagreement, however, on whether the FDA's power to regulate cell-cultured meat could come from its power to regulate "food additives," defined in the FFDCA in its relevant portion as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" and not yet be generally recognized as safe, or GRAS.[97] However, courts have further clarified that "in order to qualify as a food additive, a component must be added to a food in order to change that food's properties."[98]

Thus, because "[c]ultured meat is not added to food, it *is* the food," it is wrong to say that the FDA can regulate cultured meat because it *itself* is a food additive, but what is *added* to cells in the culturing process may qualify.[99] Because what qualifies as a "food additive" affects the FDA's

94. 21 U.S.C. §§ 392(a), 467f(a) (2018) ("Poultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act.").

95. B. George Walker, *Double Trouble: Competing Federal and State Approaches to Regulating the New Technology of Cloned Animal Foods, and Suggestions for the Future*, 14 J. TECH. L. & POL'Y 29, 49 (2009) (arguing that the CFLA excludes cell-cultured meat, or "in vitro meat," because it is not a "cloned product").

96. *See* Schneider, *supra* note 63, at 1014–15 (discussing the possible use of NADA contingent on the development of genetically modified meat).

97. 21 U.S.C. § 321(s) (2018); s*ee id.* at 1015 (arguing that cell-cultured meat is a food additive). *But see* Jennifer Penn, "*Cultured Meat": Lab-Grown Beef and Regulating the Future Meat Market*, 36 UCLA J. ENVTL. L. & POL'Y 104, 117 (2018) (arguing that cell-cultured meat is not a food additive).

98. United States v. 29 Cartons of * * * An Article of Food, 987 F.2d 33, 37 (1st Cir. 1993) (citing United States v. Two Plastic Drums, 984 F.2d 814 (7th Cir. 1993)).

99. Penn, *supra* note 97, at 108 (emphasis added).

ability to declare an additive as GRAS, it is important to identify which additives will qualify.

Arguably, the nutrient medium that is added to tissue samples to cause it to expand into what we would recognize as meat would qualify as a "food additive" because it is added to a food, namely a tissue sample, to cause that sample to change as the cells propagate. Whether this is a change in property is unclear, however. Does a change in property require some chemical change in the substance of the food, or is the extreme visual property change between a small clump of cells and a hunk of beef sufficient? Because the court does not define "properties," the law is unclear, but the FDA seems to think that it is sufficient.[100]

Clearer, however, is that other *possible* additives may qualify. Anticipated additives include gases, particularly oxygen and carbon dioxide, and "growth factors," such as cytokines, hormones, and signaling molecules.[101] Any one of these substances is sure to affect the chemical structure of the food, namely the clump of cells, that it is added to, and, thus, should qualify as a "food additive." There is a whole world of possible future developments, such as modifications to nutritional content or the development of blood vessels, that may require artificial additives that would qualify, as well.[102]

Thus, though it is not clear that the FDA has a source of authority to regulate cell-cultured meat *per se* in its *current* form, the FDA likely has authority to regulate most, if not all, of what is *added* to cells in the cell-culturing process, effectively giving it the power to regulate the cell-culturing process. However, this authority does not negate the USDA's authority, or vice versa, as the agencies share joint jurisdiction over food additives in meat.[103]

C. *The Best Authority is a New Authority*

It is worth noting that this jurisdictional murkiness is likely due to the inability of Congress, when drafting the statutes discussed above, to predict that cell-cultured meat would exist and how it would come about. The current statutes were not made to address these questions. Thus, the

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100. *See FDA Transcript*, *supra* note 2, at 39 ("[Y]ou could have the same chemical identity of a substance and yet the properties could change a great deal depending on the actual size of the particles of the substance in the food."); Penn, *supra* note 97 (emphasis added).

101. U.S. DEP'T OF AGRIC. & U.S. FOOD &. DRUG ADMIN., USDA/FDA JOINT PUBLIC MEETING: THE USE OF CELL CULTURE TECHNOLOGY TO DEVELOP PRODUCTS DERIVED FROM LIVESTOCK AND POULTRY 10, https://www.fsis.usda.gov/wps/wcm/connect/ccb77304-98ad-40c9-a05a-1e22bcf68c70/Day-1A-Morning_USDA-FDA-Joint-Meeting.pdf?MOD=AJPERES (last visited Nov. 7, 2019).

102. Schneider, *supra* note 63, at 1015.

103. *See* FORTIN, *supra* note 12, at 29.

clearest way for Congress to indicate its intentions would be to set a new framework for jurisdiction which clarifies how the agencies should approach these emerging technologies.[104] Given recent announcements however, the USDA and FDA have indicated that they have no intention of sitting on their thumbs waiting for Congress to tell them what to do.[105]

III. EVALUATING THE PROPOSED SHARED JURISDICTION OF SAFETY REGULATION OF CULTURED MEAT

The USDA and FDA's decision to transition from FDA to USDA oversight at point of harvest is the best framework possible for safety regulation of cell-cultured meat. The FDA's extensive experience with regulating cell-cultured technologies and other emerging biotechnologies make it the agency best prepared to ensure the safety of the cell-culturing process.[106] On the other hand, the USDA's extensive experience with ensuring that meats are not contaminated post-harvest make it the best agency to ensure the safety of cell-cultured meat after it is harvested, when it will likely be just as vulnerable to contaminants as traditional meats.[107] Under the newly announced framework, the agencies would share jurisdiction in a way that best ensures the safety of the final product. That said, a deeper look at arguments on each side is helpful to understanding both the reasoning for this division and how such regulation may be implemented.

A. *What Would FDA Regulation of Cultured Meat Look Like?*

The argument for sole FDA regulation relies heavily on the FDA's experience regulating similar emerging technologies. Because the FDA has worked with GMOs, cloning, and cell-culture technologies in other contexts, the FDA would likely more easily adapt its current processes for evaluating the safety of those technologies into evaluations of cell-cultured meat production. This argument is simple, but compelling. However, it is not immediately apparent how the FDA would adapt those processes.

1. Evaluate each Individual Ingredient as GRAS?

One possibility is that the FDA apply its GRAS principle. Applying the GRAS principle, if the FDA has recognized each ingredient in cell-

104. Although this paper will not explore potential statutory frameworks given that the FDA and USDA have announced intentions to share jurisdiction, several previous articles have suggested potential frameworks. *See, e.g.*, Penn, *supra* note 97, at 126; *see also* Schneider, *supra* note 63, at 1025; Walker, *supra* note 95, at 47–50.

105. *See generally supra* notes 84–92 and accompanying text.

106. *See* discussion supra Section I.A.4.

107. *See* discussion *supra* Section I.A.2.

cultured meat as safe, the FDA would consider the final product safe.[108] To some degree, this approach makes sense, as all or most of the components added during the process are likely to be common materials that are generally safe and likely already recognized under GRAS. Those ingredients that are not already addressed by GRAS would be subject to FDA investigations, which would look into the scientific processes that create them to determine their safety.

The FDA used a similar approach to declare a form of rennet (which is created using a bacteria that was genetically engineered to produce rennet and is itself another form of animal cell-culture) to be safe.[109] Rennet is an "enzyme that goes into a product that is later inspected and certified," and is thus rightly treated as a food additive.[110] Cell-culture meat, however, is certainly not a food additive itself, but a collection of possible food additives.[111] Thus, unlike rennet, cell-cultured meat will need to be composed completely of food additives that are GRAS to be GRAS itself. While the FDA's experience with rennet will likely aid in its determination of potential risks, the FDA will have to use a different process to approve cultured meat.

Further, such an approach, when applied to cell-cultured meat, fails to account for the potential, unique risks that could arise due to the cell-culture process. One concern is that, if a pathogen makes its way into the bioreactor due to improper sanitary procedures, it could feed on the nutrient medium and propagate along with the cells, infecting an entire batch of the meat.[112] Notably, a similar concern applies to traditional meats as the contaminated meat of one cow, chicken, etc., may contaminate an entire batch of ground beef, chicken nugget mixture, etc., when mixed together.[113] While such a contaminant will ideally be caught

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108. Determination of whether a new ingredient is GRAS is "based only on the views of experts qualified by scientific training and experience" through "scientific procedures" which "shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods." 21 C.F.R. § 170.30(a)–(b) (2019).

109. "Rennet" is a "mixture of enzymes that turns milk into curds and whey in cheesemaking," which traditionally was "extracted from the inner lining of the fourth stomach of calves." *What is Cellular Agriculture?*, NEW HARVEST, https://www.new-harvest.org/cell_ag_101 (last visited Nov. 6, 2019).; *id*.; *see also* Penn, *supra* note 97, at 116.

110. Penn, *supra* note 97, at 116.

111. *See* discussion *supra* Section II.B.

112. *See, e.g.*, *FDA Transcript*, *supra* note 2, at 74–75.

113. "Foods that mingle the products of many individual animals, such as . . . ground beef, are particularly hazardous because a pathogen present in any one of the animals may contaminate

in an inspection at harvest, if not before, the hand of regulators should be there to ensure that the process does not create new risks that will need to be evaluated for their safety, just as it is with traditional meats. Thus, cell-cultured meat should not be immediately regarded as GRAS, even if its ingredients are all GRAS.

2. Declare Cultured and Traditional Meat Substantially Equivalent?

Another possibility is that the doctrine of substantial equivalence could be applied to cell-cultured meats, just as it is with genetically engineered crops, better known as "GMOs." The doctrine of substantial equivalence allows the FDA to approve as *safe* foods that are substantially equivalent to existing GRAS foods.[114] Since the FDA's conclusion in 1992 that, in "most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food," the FDA "presumes that most [genetically engineered] foods are GRAS."[115] Evaluated under this framework, GMOs are exempt from "premarket review."[116]

Applying the doctrine to cell-cultured meat, the FDA could say that cell-cultured meat is safe if it is substantially equivalent to its traditional meat counterparts. Arguably, like most GMOs, cell-cultured meat will be substantially equivalent to the form of traditional meat it was derived from because the cells in the final product will be genetically identical to the original sample.[117]

However, producers are likely to make varying degrees of alterations, both intentional and unintentional, to the cells during production. For instance, producers may intentionally leave out pharmaceutical residues, alter fat content, or add artificial blood vessels to the cultured meat.[118] If

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the whole batch. A single hamburger may contain meat from hundreds of animals. . . . A broiler chicken carcass can be exposed to the drippings and juices of many thousands of other birds that went through the same cold water tank after slaughter." CTR. DISEASE CONTROL, FOODBORNE ILLNESS: FREQUENTLY ASKED QUESTIONS 9 (Jan. 10, 2005), http://www.townofdurhamct.org/filestorage/28562/27556/27707/27719/03-26-2010_Health_Dept_foodborne.pdf.

114. *See* Trevor Findley, *Genetically Engineered Crops: How the Courts Dismantled the Doctrine of Substantial Equivalence*, 27 DUKE ENVTL. L. & POL'Y F. 119, 125–28 (2016) (discussing the nature and origin of the doctrine of substantial equivalence); FORTIN, *supra* note 12, at 286 (describing substantial equivalence as an analytical tool, important for determining safety of foods).

115. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992); Trevor Findley, *Genetically Engineered Crops: How the Courts Dismantled the Doctrine of Substantial Equivalence*, 27 DUKE ENVTL. L. & POL'Y F. 119, 123 (2016).

116. Schneider, *supra* note 63, at 1007.

117. *See* discussion *supra* Section II.B.1.

118. *See* discussion *supra* Section II.B.2.

such changes are made, the doctrine of substantial equivalence should not apply.[119] Moreover, the lab setting may introduce new contaminants not found in traditional meats.[120] In such instances, the doctrine of substantial equivalence again should not apply because the risks associated with the food change substantially and will need separate approval. Ultimately, the FDA should only find that cell-cultured meat is substantially equivalent to its counterpart if it is proven that producers have not added any ingredients or contaminants that are not already found in traditional meats.

B. *The Pre- vs. Post-Harvest Contaminant Problem*

Supporters of granting FDA sole jurisdiction often rely on the argument that the lab setting used in the production of cultured meat will reduce the likelihood of contamination, so there is no need to heavily regulate production process itself, as long as the final product can be ensured as safe.[121] This argument certainly has some validity as the laboratory setting of cell-cultured meat harvest is likely to be a cleaner, more controlled environment than is found in the slaughterhouses where traditional meat is harvested. Traditional meat risks contamination at the time of slaughter due to cross-contamination between meat and fecal matter from other portions of the animal, such as the hide, intestines, and rectum.[122] In light of this dynamic, supporters of granting the FDA sole jurisdiction argue that the FDA's focus on the safety of final products and laxer regulations are appropriate.[123]

After harvest, cell-cultured meat will still need to be inspected, separated, packaged, and transported in a fashion likely similar to traditional meat. Laboratory setting or not, the possibility for cross-

119. Schneider, *supra* note 63, at 1015.

120. *See* discussion *infra* Section III.B.

121. *See, e.g.*, Linda MacDonald Glenn & Lisa D'Agostino, *The Moveable Feast: Legal, Ethical, and Social Implications of Converging Technologies on Our Dinner Tables*, 4 NE. U. L.J. 111, 124–25 (2012) ("It is vastly easier to monitor a food production operation than a farm. By moving the operation from the feedlot to the factory, there is the opportunity for better FDA oversight.").

122. *See* Farzaneh Bakhtiary et al., *Evaluation of Bacterial Contamination Sources in Meat Production Line*, 39 J. FOOD QUALITY 750 (2016) ("Bacterial spoilage of meat depends on the initial number of microorganism, time/temperature combination of storage conditions and physicochemical properties of meat. Mostly, contamination occurs because of inadequate hygienic conditions and handling in slaughterhouses, moreover the attachment properties and the biofilm formation of bacteria on surfaces facilitate cross-contamination. Preslaughter conditions like feeding and housing including spreadable contaminations from skin and feces, contents of digestion system, and contaminated water are sources of Staphylococcus, Escherichia and Bacillus cereus. Different processes in slaughterhouses like evisceration can contaminate carcasses and equipment with gut bacteria.").

123. *See FDA Transcript*, *supra* note 2.

contamination still exists. Surfaces, workers, clothing, and even the air can be shared between potentially contaminated samples and final products. While a laboratory setting may more easily satisfy USDA standards of cleanliness, etc., the setting should still be inspected to ensure that such cross-contamination is limited as much as possible.[124]

After leaving the laboratory-like production setting, cell-cultured meat, may be vulnerable to contaminants which cause foodborne illness in traditional meat, such as *Salmonella* and *E. coli*.[125] The USDA is best suited to inspect these production areas to ensure that safety protocols are followed, limiting cross-contamination. It is therefore fitting that the current agreement requires standard USDA safety inspections of cultured meat production facilities.[126]

C. *The Value of Split Jurisdiction at Harvest*

Although it is yet unclear how the FDA will regulate cell-cultured meat, the FDA's experience in cell-culture and other biotechnologies, and the likelihood of limiting exposure to contaminants pre-harvest, make it the most appropriate agency to efficiently evaluate the safety of cell-cultured meat up to the point of harvest. However, because cell-cultured meat will in essence be considered "meat" after harvest, it will likely be just as vulnerable to post-harvest contaminants as traditional meat. As compared to the FDA, the USDA has greater experience and capabilities to handle such risks. Splitting the power to regulate cell-cultured meat at the point of harvest is the best way to utilize the strengths and experience of both the FDA and USDA, ensuring efficient and safe regulation. However, the value of this dynamic ends at the point of labeling.

IV. EVALUATING THE PROPOSED USDA LABELING REGULATION OF CULTURED MEAT

Perhaps the most hotly contested issue concerning the regulation of cultured meat has been what to call it. As a result, there has been a great deal of debate over which agency should regulate labeling and what limits should be put in place.

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124. 9 C.F.R. § 416 (2019).

125. *Foods That Can Cause Food Poisoning*, CTR. FOR DISEASE CONTROL, https://www.cdc.gov/foodsafety/foods-linked-illness.html (last modified Oct. 11, 2019).

126. *See* USDA AND FDA CULTURED MEAT MOU, *supra* note 78, at 3 ("USDA-FSIS will . . . [c]onduct inspection in establishments where cells cultured from livestock and poultry subject to the FMIA and PPIA are harvested, processed, packaged or labeled, in accordance with applicable FSIS regulations (including sanitation and physical product inspection, Hazard Analysis and Critical Control Point (HACCP) verification, product testing, and records review), to ensure that resulting products are safe, unadulterated, wholesome and properly labeled.").

There is often a seeming contradiction within these arguments. Cultured meat producers often argue that their product is similar enough to "meat" for it to bear the label "meat," but they simultaneously argue that their product is not "meat" under the statute which would allow USDA authority.[127] Conversely, traditional meat producers often argue that cultured meat is not "true" meat, and that allowing cultured meat to employ "meat" language misleads consumers and damages their brand, but they simultaneously argue that cultured meat falls under the statutory definition of "meat," such that it would fall under USDA authority.[128] Of course, both arguments have their strengths and weaknesses, but their apparent inconsistencies shed light on an irony within this discussion: is it "meat," or not?

A. *Policy and Constitutional Labeling Concerns*

1. Misleading Consumers

Arguably the most important consideration when determining whether a particular food is properly labeled is whether the label would mislead consumers. With this in mind, cultured meat should be labeled in a way that makes it clear that cultured meat is not traditional meat, but that it is almost chemically identical to its traditional form.

There will inevitably be people who, at least at first, will refuse to buy or eat cultured meat. They will want *clear* labeling that indicates to them whether meat is cultured or traditional. They would likely be very upset

127. Elaine Watson, *Cell-based Meat Cos: Please Stop Calling Us 'Lab-Grown' Meat… and We don't Use Antibiotics in Full-Scale Production*, FOOD NAVIGATOR-USA (Oct. 25, 2018, 4:33 PM), https://www.foodnavigator-usa.com/Article/2018/10/25/Cell-based-meat-cos-Please-stop-calling-us-lab-grown-meat-and-we-don-t-use-antibiotics-in-full-scale-production (providing a statement from Peter Licari on behalf of JUST, a supporter of cell-cultured meats: "With regard to labeling . . . we believe there should be both a regulatory nomenclature (e.g., statement of identity) and consumer-facing nomenclature that sufficiently differentiates cell-cultured products from traditional meat products but appropriately acknowledges these products as meat.").

128. *See id.* (providing a statement from meat producers, including: Kevin Kester on behalf of the National Cattlemen's Beef Association: "The FDA has consistently show it is unwilling or unable to enforce product labeling standards. The agency has turned a blind eye to labeling abuses from fake milk manufacturers for nearly three decades. Lab grown fake meat manufacturers must not be permitted to use the term beef and any associated nomenclature. It should only be applicable to livestock raised by farmers and ranchers." Danni Beer on behalf of the U.S. Cattlemen's Association: "We believe that cell-cultured proteins should be regulated as strictly as beef, but that these products should have their own food category and inspection process, not using our stamp or shield. The alternative protein industry should not be allowed to villainize the beef cattle industry. We should have standards of identity to establish these products as different from meat or beef . . . Consumers . . . think of what we're doing as families taking care of the land, taking care of the cattle everyday . . . they don't think about somebody putting a group of cells together and growing a new product. That's not beef.").

to learn that something labeled simply "beef" was not meat taken from a once-living cow, as they expect it to be. Further, some people will actually seek out cultured meat. Whether for dietary, environmental, or moral reasons, or simply out of curiosity, those seeking out cultured meat will want to be able to quickly identify and distinguish it from traditional meat. Thus, both those wishing to seek out and those wanting to avoid cultured meat will want labeling to provide clear identification. It would mislead both groups to simply call cultured beef "beef" or cultured chicken "chicken" without some modifier indicating its origin.

However, to not allow cultured beef to call itself "beef" at all could be dangerous. Most importantly, a significant portion of the population is allergic to certain meats.[129] Individuals with meat allergies will almost certainly be allergic to the cultured version of those meats, as well, as the two versions will be nearly chemically identical. These people *need* labeling that clearly indicates that cultured beef is "beef" and cultured chicken is "chicken." If modifiers such as "imitation beef" or "artificial chicken" are applied, or if regulators prohibit cultured meat producers from using terms like "beef" or "chicken" altogether, it is possible that people may mistakenly consume cultured meat, wrongly assuming that it is something akin to the plant-based proteins that already exist. In order to protect the interests of consumers, it is crucial that labelling clearly distinguished cultured meat from plant-based proteins.

2. Overburdening Producers

Regulators must not overburden producers when determining proper labeling restrictions for cultured meat due to policy and First Amendment considerations. While the First Amendment's protection of the freedom of speech includes protections for "commercial speech," the Court has held that there is a "'commonsense' distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech."[130] Accordingly, "courts have found that the government can prohibit misleading speech, require manufacturers to display commercial messages in certain forms, and include additional information, warnings,

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129. *See* Jeffrey M. Wilson & Thomas A.E. Platts-Mills, *Meat Allergy and Allergens*, MOLECULAR IMMUNOLOGY 107, 111 (2018) ("Despite traditionally being considered rare, meat allergy is being increasingly recognized in subjects of all ages.").

130. "Congress shall make no law . . . abridging the freedom of speech." U.S. CONST. amend. I; "Courts have characterized food labels as 'commercial speech.'" Melissa M. Card, *America, You are Digging Your Grave with Your Spoon-Should the FDA Tell You That on Food Labels?*, 68 FOOD & DRUG L.J. 309, 313 (2013); Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm. of N.Y., 447 U.S. 557, 562 (1980).

or disclaimers."[131] This means that while regulators do in fact have the power to regulate misleading labels, they must be careful to not infringe upon cultured meat producers' right to free speech.[132]

Regulators should take care not to overburden cultured meat producers in labeling restrictions for policy reasons, as well. If cultured meat is prevented from using the same terms used to describe traditional meat (such as "beef" and "chicken") all together, or is required to bear a modifier such as "artificial," "imitation," or even "lab-grown" that conveys a negative, undesirable tone, regulators risk alienating consumers from the beginning. Given the world of possibilities cultured meat presents, this would be a grave mistake.

Finally, it should be noted that regulators should keep fairness in mind, as well. Plant-based proteins made to imitate meats already use terms like "meat," "beef," "chicken," and "burger" to describe what they are imitating—they are simply required to provide some form of qualifier, such as "vegetarian," "garden," "meatless," "plant-based," or "soy," which indicates to the consumer that this is not actually meat.[133] Given that plant-based protein producers can place neutral and even positive qualifiers on "meat" language without confusing consumers, why not allow cultured meat producers to do the same?

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131. Card, *supra* note 130, at 312–13.

132. Some states, such as Missouri, have already run into First Amendment problems with broad statutes that prevent both cultured meat and plant-based meat substitutes from using meat language. *See, e.g.*, Amie Tsang, *What, Exactly, Is Meat? Plant-Based Food Producers Sue Missouri over Labeling*, N.Y. TIMES (Aug. 28, 2018), https://www.nytimes.com/2018/08/28/us/missouri-meat-law-tofurky.html (reporting on a First Amendment suit over a Missouri statute that prohibits "misrepresenting a product as meat that is not derived from harvested production livestock or poultry"); Sam Bloch, *Lawmakers in Nebraska, Wyoming, and Virginia Say if it's Not a Carcass, Then it's "Imitation,"* THE NEW FOOD ECONOMY (Jan. 28, 2019), https://newfoodeconomy.org/missouri-nebraska-cell-cultured-plant-based-meat-labeling/ (reporting on statutes in Nebraska, Wyoming, and Virginia that are "following in the footsteps" of the Missouri law); Nathaniel Popper, *You Call That Meat? Not so Fast, Cattle Ranchers Say*, N.Y. TIMES (Feb. 9, 2019), https://www.nytimes.com/2019/02/09/technology/meat-veggie-burgers-lab-produced.html?smid=nytcore-ios-share (reporting on similar, newly-introduced meat-labeling bills in Arizona and Arkansas as well as past, similar bills in Virginia, Washington, and Nebraska).

133. *See, e.g.*, Adam Bryan, *16 Popular Fake Meat Brands – The Complete List of Products (2020)*, URBAN TASTEBUD, https://urbantastebud.com/fake-meat-brands/ (last visited Feb. 10, 2020) (providing examples of names of plant-based proteins and brand names, including: "Beyond Meat," "beef-less ground beef," "meatless meatballs," "garden veggie burger," "smoky chipotle meatless chicken," and "soy chorizo"); *Deli Slices*, TOFURKY, https://tofurky.com/what-we-make/deli-slices/hickory-smoked/ (last visited Feb. 10, 2020) ("Hickory Smoked Plant-Based Deli Slices"); Marissa Miller, *The 15 Best Vegetarian and Vegan Meat Substitutes* WOMEN'S HEALTH (Dec. 10, 2018), https://www.womenshealthmag.com/food/a19914260/best-meat-substitutes/ ("Vegetarian Grain Meat Sausages").

B. *Statements of Identity*

With these considerations in mind, we must again ask: what should we call cultured meat? Both the USDA and FDA will find that a food is "misbranded" if it does not prominently display its "statement of identity."[134] For some foods, statements of identity are "specified in or required by . . . [f]ederal law or regulation" and must comply with the definitions set in those laws to use those statements of identity.[135] If there is no such applicable law or regulation, the statement of identity must be a "common or usual name of the food," if one exists.[136] If there is no common or usual name, then the statement of identity must be "[a]n appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food."[137]

1. Statutory or Regulatory Statement of Identity

Currently, there is no statutory or regulatory statement of identity that should be applied to cultured meat. When a plant-based protein refers to itself as "meatless chicken" or "beef-less ground beef," the statements of identity which apply to traditional meats are not breached.[138] As such, when cultured meat refers to itself as "cultured chicken" or "cultured ground beef," the statements of identity should not be implicated. In both cases, the modifiers applied indicate a deviation from the term's normal application in a way that the consumer would understand.

This argument is similar to that made by "soy milk," "almond milk," and "coconut milk" producers in defense of their use of the term "milk" in their statements of identity.[139] The FDA has recognized that there is a statement of identity that applies to "milk" which is limited to milk obtained from cows.[140] This recognition makes sense in that, when someone refers to "milk" without modifying the statement, they are usually referring to cow's milk. Thus, if something is simply labeled "milk" in a supermarket, the typical consumer will assume that it is cow's

134. *See* 21 C.F.R. § 101.3(a)–(e) (2019) (establishing FDA's food statement of identity requirement); *see also* 9 C.F.R. § 319.1(a) (USDA's meat product statements of identity requirement); *see also* 9 C.F.R. § 381.1(b) (USDA's poultry product statements of identity requirement).

135. 21 C.F.R. § 101.3(b)(1); *see also* U.S. DEPT. OF AGRIC., A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 28–29 (2007), https://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES [hereinafter USDA LABELING GUIDE].

136. 21 C.F.R. § 101.3(b)(2); *see also* USDA LABELING GUIDE, *supra* note 135, at 29.

137. 21 C.F.R. § 101.3(b)(3); *see also* USDA LABELING GUIDE, *supra* note 135, at 29–30.

138. *See* Bryan, *supra* note 133 and accompanying text.

139. *See* Ang v. Whitewave Foods Co., No. 13-CV-1953, 2013 WL 6492353, at *4 (N.D. Cal. Dec. 10, 2013) (unreported).

140. 21 C.F.R. § 131.110(a) (2019).

milk. However, the same consumer will understand that "soy milk" was not obtained from a cow, even if he or she does not understand exactly how similar "soy milk" is to "milk." The addition of the modifier changes the meaning of the otherwise recognized term "milk" in a way that does not mislead consumers and, thus, is allowed. However, this has not stopped "milk" producers from contesting the FDA's policy of allowing such labeling.[141]

Although these "milk" suits have not been successful, the FDA has agreed to review its policy out of "concerns that the labeling of some plant-based products may lead consumers to believe that those products have the same key attributes as dairy products, even though these products can vary widely in their nutritional content."[142] This concern is based on "significant health consequences—contributing to under consumption of key nutrients, such as calcium and vitamin D for which dairy products are good sources in the U.S. population."[143] Although this statement does throw into question whether the FDA will continue its policy of allowing terms like "almond milk" to be used, it also clarifies that the FDA's concerns are not focused on misleading consumers as to the origin of the products, but rather of their relative nutritional content. The FDA is simply not concerned that consumers will believe that "almond milk" is derived from cows. Instead, the FDA is concerned that consumers will believe "almond milk" is a sufficient nutrient replacement for cow's milk.

In contrast to plant-based dairy products, cultured meat should not, in its basic form, have any significant nutritional deviation from traditional meats because the cells will be genetically identical.[144] Thus, there should be no concern that consumers will be misled as to the nutritional value of cultured meats. Moreover, any changes to the nutritional value of cultured meat should be beneficial, incentivizing producers to advertise those changes.[145] The FDA's current policy of recognizing that labeling modifiers affect the meaning of the statements of identity in a way that informs the consumer as to their origins should be maintained. Thus, similar modifiers should be allowed to distinguish cultured meat from traditional meat in a way that does not mislead consumers.

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141. *See supra* note 26 and accompanying text.

142. *See Ang*, 2013 WL 6492353, at *4; U.S. FOOD & DRUG ADMIN., STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D., ON MODERNIZING STANDARDS OF IDENTITY AND THE USE OF DAIRY NAMES FOR PLANT-BASED SUBSTITUTES (Sept. 27, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm621824.htm.

143. *Id.*

144. *See* discussion *supra* Section II.B.1.

145. *See supra* notes 59–61 and accompanying text.

Thus, regardless whether current statutory or regulatory statements of identity currently apply, or if new statements of identity are created that would apply, to traditional meat forms, cultured meat producers should be allowed to use such statements of identity as long as there is some modifier added which would distinguish them from their traditional form in a way that consumers will understand the differences between the products.

2. Common or Usual Name

Because no statute or regulation establishes statements of identity for cultured meats, the next step is to determine whether there exists a common or usual name that could be used as a statement of identity. Simply put, there are no such common or usual names. As established, cultured meat currently goes by a wide variety of names depending on who is describing it.[146] Moreover, since cultured meat has not yet experienced large-scale production, many do not even know that it exists, and would therefore not know what to call it. As such, there is no common or usual name that could be properly applied as a statement of identity for cultured meats.

3. Descriptive Term

A statement of identity for cultured meat must be a descriptive term, but one must ask: What term would be appropriate?[147] Some cultured meat producers and supporters argue that the term "clean meat" is appropriate because their product will be made without pharmaceutical residues, contaminants, etc., that are found in some traditional meats.[148] Traditional meat producers vehemently oppose the term "clean meat" because, they argue, it implies that traditional meat is "dirty."[149] Given that cultured meat may open itself to new methods of contamination, and the overall relative safety of cultured meat is yet unknown, this is a fair

146. *See supra* notes 2–5 and accompanying text.

147. There is no proper "fanciful" term here to be applied. Thus, a descriptive term alone must be used.

148. *See Clean Meat Basics*, CELLMOTIONS, https://www.cellmotions.com/pages/clean-meat-basics (last visited Jan. 19, 2020) ("Animal agriculture is unsustainable, environmentally harmful, bad for human health, and bad for animals. Clean meat mitigates or solves these problems."); s*ee, e.g.*, Bruce Friedrich, *"Clean Meat": The "Clean Energy" of Food*, GOOD FOOD INST. (Sept. 6, 2016), https://www.gfi.org/clean-meat-the-clean-energy-of-food (demonstrating that The Good Food Institute, a promoter of cultured meat and its producers, refers to clean meat in this way).

149. *See, e.g.*, Candice Choi, *Meat 2.0? Clean Meat? Spat Grows over Food Wording*, DET. NEWS (June 20, 2018), https://www.detroitnews.com/story/business/2018/06/19/meat-clean-meat-spat-grows-food-wording/36184473/ ("'It implies that traditional beef is dirty,' says Danielle Beck, director of government affairs for the National Cattleman's Beef Association.").

criticism.[150] Moreover, the modifier "clean" does not indicate to the consumer that the method of production has changed and therefore risks misleading consumers. Consumers may believe, for instance, that "clean" indicates that it is simply pharmaceutical residue-free or pathogen-free but still harvested straight from once-living animals. Since consumers care about such distinctions, "clean" is not an appropriate modifier to indicate the deviation from the typical understanding of "meat," "beef," "chicken," etc.[151]

Traditional meat producers, on the other hand, often argue that, if cultured meat is allowed to use "meat" language at all, it should bear a modifier that would indicate that it is not *truly* meat, such as "faux," "imitation," "artificial," or "synthetic."[152] However, these terms similarly fail to adequately inform consumers about what they are eating. Consumers require notice that cultured meats are, with the exception of their method of production, identical to their traditional meat counterparts; otherwise, regulators risk exposing consumers to dangerous allergens.[153] Moreover, use of these terms risk overburdening cultured meat producers, in ways which implicate both policy and First Amendment concerns.[154] Furthermore, the term "imitation" has its own legal definition which cannot apply to cultured meat.[155]

The descriptive term used to modify cultured meat should be one that indicates its method of production. Although the modifier "lab-grown" properly informs consumers on the method of production, requiring producers to label their product with a term that has an arguably negative tone is arguably too burdensome.[156]

"Cultured," on the other hand, has a neutral tone but still notifies consumers of the origin of the meat. The term indicates that cultured meat is meat without misleading the consumers into believing that they are purchasing traditionally produced meat. Further, because of its neutral tone, "cultured" does not overburden producers in a way that may be

150. *See* discussion *supra* Section III.B.

151. *See* discussion *supra* Section IV.A.1.

152. *See FDA Transcript*, *supra* note 2, at 161 ("The United States Cattlemen's Association . . . believe[s] that the term meat pertains exclusively to a protein food product that was harvested from the flesh of an animal in a traditional manner. Cultured cell protein would not be included in this definition.").

153. *See* discussion *supra* Section IV.A.1.

154. *See* discussion *supra* Section IV.A.2.

155. "Imitation" products "resemble" but are "nutritionally inferior to the standardized product." USDA LABELING GUIDE, *supra* note 135. There is no incentive for cultured meat producers to alter cultured meat to be nutritionally inferior to the traditional products that they are derived from. Thus, it would be improper for the label to be applied in absence of evidence of a cultured meat producer's intention to create a nutritionally inferior product.

156. *See* discussion *supra* Section IV.A.2.

harmful to progress, potentially unfair, and constitutionally suspect.[157] Thus, "cultured" is the best modifier to use as a descriptive term in statements of identity for cultured meat.

C. *FDA or USDA Labeling Control?*

I turn now to the question: Which agency should regulate labeling of cultured meat? Arguably, the FDA is better suited to regulate cultured meat products for the same reason that it is better suited to regulate the safety of cultured meat products pre-harvest—because it has experience in regulating other forms of biotechnology such as genetic engineering, other cultured foods, etc., which could be applied to cultured meat. For example, the FDA already has a system in place to evaluate whether a genetically modified piece of corn requires special labeling identifying it as genetically modified.[158] On the other hand, the USDA is arguably better suited to regulate cultured meat labeling because it already has a system in place to regulate traditional meats. Meat grading is one example of these important USDA functions.[159]

Based on the above considerations, the best option is to allow the FDA to determine whether a given cultured meat product qualifies as "cultured meat" as defined by the recognized statement of identity.[160] The FDA would additionally be responsible for determining, based on their investigation of the safety of the product pre-harvest, if the product requires any sort of warning regarding its production methods. The USDA would then grade the cultured meat, regulate its nutrition facts, require portions of labels, etc., as they would for a traditional meat product of the same kind.

However, under the current agreement, the USDA will require cultured meat producers to seek preapproval of labelling as they do with traditional meats.[161] This requirement would make sense if cultured meat products properly fell under current USDA standards of identity, but they do not.[162] The FDA is better suited to determine whether the product violates a standard of identity and to develop a new standard of identity.

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157. *See* discussion *supra* Section IV.A.2.

158. "No special federal labeling requirements exist for GE food products if they meet the standard of substantial equivalence." Schneider, *supra* note 63, at 1007.

159. *See* Armour & Co. v. Ball, 468 F.2d 76, 81 (6th Cir. 1972) ("[O]ne purpose of the Wholesome Meat Act is to empower the Secretary to adopt definitions and standards of identity or composition so that the 'integrity' of meat food products could be 'effectively maintained.'").

160. *See* discussion Section V.B.

161. *See* USDA AND FDA CULTURED MEAT MOU, *supra* note 78, at 3 ("USDA-FSIS will . . . [r]equire that the labeling of human food products derived from the cultured cells of livestock and poultry be preapproved and then verified through inspection, as required by FSIS regulations.").

162. *See* discussion *supra* Section IV.B.1.

Thus, while the USDA may still require its mark of inspection, it should not require premarket approval for *all* labelling.

CONCLUSION

The road to mass production and distribution of cultured meat is going to be bumpy. The science is not quite to a point where cultured meat can be produced efficiently. Even once the science catches up, obstacles will still remain, such as the problem of actually convincing people to eat cultured meat, subject to the "ick factor."[163] Government agencies should be prepared, however, to quickly, but safely get these products on the market once they are in mainstream production. The potential benefits of this technology are too great to justify any delay longer than necessary to ensure consumer safety.

Because both the USDA and FDA have claimed jurisdiction over cultured meat, it is important to sort out the likely complex regulatory framework of regulation prior to cultured meat becoming market ready. By holding public meetings and announcing their proposed framework for agency jurisdiction of cultured meat, the USDA and FDA have taken the first step in accomplishing just that, but much is still unknown about how these products will be regulated.

Because the USDA and FDA's proposed framework properly designates the FDA to regulate the safety of cultured meat pre-harvest, the FDA needs to begin work now to determine how cultured meat will fit into its current policies, as this is presently unclear. The FDA should further be responsible for regulating post-harvest safety of cultured meat versions of the wild game and seafood that it currently regulates. Excepting these meats, the proposed framework further properly designates the USDA to regulate the safety of cultured meat post-harvest generally, because, after this point, cultured meat is effectively identical to and likely subject to the same or similar vulnerabilities as traditional meat.

The proposed framework is flawed, however, in that it improperly designates the USDA as sole regulator of cultured meat labeling. The FDA is better equipped to designate whether cultured meat products apply to a new statement of identity for the products, which should include the modifier "cultured," and to determine whether the products require some form of warning label. However, the USDA is well-equipped to label cultured meat in other fashions as it would traditional

163. One online survey found that, "although most respondents were willing to try in vitro meat, only one third were definitely or probably willing to eat in vitro meat regularly or as a replacement for farmed meat." MATTI WILKS & CLIVE J. C. PHILLIPS, ATTITUDES TO *IN VITRO* MEAT: A SURVEY OF POTENTIAL CONSUMERS IN THE UNITED STATES 1 (Stephanie S. Romanach ed., 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5312878/pdf/pone.0171904.pdf.

meats, including grading and regulating nutrition facts. Thus, the agencies should split jurisdiction of labeling cultured meat as well.