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The Fight Over Frankenmeat: the FDA as the Proper Agency to Regulate Cell-Based "Clean Meat"

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THE FDA AS THE PROPER AGENCY TO REGULATE CELL-BASED "CLEAN MEAT"

"*We shall escape the absurdity of growing a whole chicken in order to eat the breast or wing, by growing these parts separately under a suitable medium . . . . The new foods will be practically indistinguishable from the natural products from the outset, and any changes will be so gradual as to escape observation . . . . Parks and gardens will cover our pastures and plowed fields*."[1]

INTRODUCTION

In the past several years, there has been a notable increase in the demand for nonanimal sourced meat, dairy, and egg alternatives.[2] Individuals around the world, motivated by a range of environmental, ethical, and health concerns, are increasingly adopting a fully or partially plant-based diet.[3] In the United States alone, sales of plant-based foods grew 29 percent since 2017, while total U.S. retail food sales grew just 4 percent during that same period.[4] In 2020, the market for plant-based meat—which refers to products "made from plants . . . . designed and created to look like, taste like, and cook like conventional meat"[5]—was worth $1.4 billion, and 18 percent of all U.S. households have purchased a plant-based meat alternative.[6]

These trends have spurred unprecedented innovation in the food industry, as companies invest in developing products

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[1] Winston Churchill, *Fifty Years Hence*, POPULAR MECHANICS, Mar. 1932, at 390, 397.

[2] *U.S. Retail Market Data for the Plant-Based Industry*, GOOD FOOD INST., https://www.gfi.org/marketresearch [https://perma.cc/F9CN-5JGS].

[3] Zee Krstic, *Sales Show That More People Are Eating Plant-Based Foods—And Not Just Vegetarians*, COOKINGLIGHT (Aug. 7, 2018), https://www.cookinglight.com/news/plant-based-foods-more-popular-than-ever [https://perma.cc/RZ56-LT8Z]; Laura Reiley, *From Lab to Table: Will Cell-Cultured Meat Win Over Americans?*, WASH. POST (May 3, 2019, 7:11 PM), https://www.washingtonpost.com/business/2019/05/03/lab-table-will-cell-based-meat-win-over-americans/?noredirect=on [https://perma.cc/Z4W2-K6EU].

[4] *See U.S. Retail Marekt Data for the Plant-Based Industry*, *supra* note 2.

[5] Stephanie Osmanski, *What is Plant-Based Meat?*, GREENMATTERS, https://www.greenmatters.com/p/plant-based-meats [https://perma.cc/QX7B-DW4R].

[6] *See U.S. Retail Market Data for the Plant-Based Industry*, *supra* note 2.

untainted by the growing stigma against traditionally raised and slaughtered meat products.[7] Consequently, the food technology envisioned by Winston Churchill in his 1932 article *Fifty Years Hence* is no longer a sci-fi fantasy, thanks to the development of so-called "clean meat," which is "a term used to indicate real meat produced by in vitro cultivation of animal cells, without the need to slaughter any animal."[8]

While some existing meat producing companies are, themselves, investing in the development of innovative plant-based or lab-grown meat products,[9] the animal agriculture industry has generally reacted to the strength and growth in market share of non-animal sourced meat, dairy, and egg products with attempts to deter consumers from purchasing them and to influence the regulatory landscape for these products.[10] One method of doing so involves working to ensure that plant-based foods are labeled differently than their animal-sourced counterparts.[11] With respect to alternative meat products, "[b]ills to prevent plant-based and/or cell-cultured products from being labeled as 'meat' or 'beef' have [already] been introduced in [twenty-five] [U.S.] states, and have already passed in . . . Mississippi, Oklahoma, Arkansas, Missouri, Montana, South Carolina, North Dakota and South Dakota."[12] While these bills implicate similar First Amendment concerns to the DAIRY PRIDE Act and other legislation around terminology,[13] the concern with

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[7] *See* Krstic, *supra* note 3; Zee Krstic, *Tyson Will Add Vegan Proteins to Meat Counters Nationwide This Year*, COOKINGLIGHT (Feb. 12, 2019), https://www.cookinglight.com/news/tyson-vegan-protein-meat [https://perma.cc/LSN3-J943] [hereinafter Krstic, *Vegan Proteins*].

[8] *See* Churchill, *supra* note 1; Davide Banis, 7 *Predictions on the Future of Clean Meat in 2019*, FORBES (Dec. 14, 2018, 6:42 AM), https://www.forbes.com/sites/davidebanis/2018/12/14/7-predictions-on-the-future-of-clean-meat-in-2019/#6bd7c17d3a99 [https://perma.cc/4YV6-SBG8]. I will continue to use the terms "clean meat" and lab-grown meat throughout this note to discuss the type of cell-cultured meat product that is the subject of this analysis.

[9] *See* Krstic, *Vegan Proteins*, *supra* note 7.

[10] *See* Reiley, *supra* note 3; Frank Morris, *Big Beef Prepares for Battle, As Interest Grows in Plant-Based and Lab-Grown Meats*, NPR (Dec. 18, 2018, 2:02 PM), https://www.npr.org/sections/thesalt/2018/12/18/677581085/big-beef-prepares-for-battle-as-interest-grows-in-plant-based-and-lab-grown-meat [https://perma.cc/V5NJ-429N].

[11] *See* Morris, *supra* note 10.

[12] Elaine Watson, *Plant-Based and Cell-Cultured 'Meat' Labeling Under Attack in 25 States*, FOOD NAVIGATOR-USA, (July 29, 2019, 8:34 AM), https://www.foodnavigator-usa.com/Article/2019/05/29/Plant-based-and-cell-cultured-meat-labeling-under-attack-in-25-states?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright [https://perma.cc/W25F-WDX2].

[13] Matt Ball, *GFI Goes to Court for First Amendment*, GOOD FOOD INST.(Aug. 27, 2018), https://www.gfi.org/gfi-goes-to-court-for-first-amendment [https://perma.cc/TV92-C25Y]. The DAIRY PRIDE Act would prohibit plant-based milk and cheese producers from using any dairy specific words to describe their products in their packaging or advertising. This prohibition is a content-based commercial speech restriction which runs counter to the First Amendment of the Constitution and impedes these producers' free speech rights. Kathleen Justis, *Lactose's Intolerance: The Role of Manufacturers' Rights and Commercial Free Speech in Big Dairy's Fight to Restrict Use of the Term "Milk,"* 84 BROOK. L. REV. 999, 1002 (2019).

respect to labeling of lab-grown clean meat is different than concerns relating to plant-based products because clean meat is biologically and nutritionally "meat." Additionally, while plant-based meat alternatives have long been available to consumers, clean meat is not yet available on grocery store shelves.[14]

The controversy over how to label clean meat is part of a wider issue, namely, which agency will oversee the development of regulation for the burgeoning industry.[15] In 2019, the Food and Drug Administration (FDA, or the Agency) and the United States Department of Agriculture (USDA, or the Department), through the Department's subsidiary body, the Food Safety and Inspection Service (FSIS), publicly announced that they will share regulatory oversight of clean meat.[16] The agreement between the two agencies "recognize[s] that each Party has an important role in the oversight of human food" and formalizes "the Parties' shared commitment to (1) ongoing cooperation to refine the details regarding the Parties' respective roles to provide for comprehensive and coordinated oversight and (2) a joint process by which the Parties will identify any changes needed to statutory or regulatory authorities to effect the intended regulatory oversight."[17] The agreement bases the FDA's role in the proposed shared oversight structure on the Federal Food, Drug, and Cosmetic Act (FDCA), and it bases the USDA's role on the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), among others.[18]

The agreement notes that the FDA is responsible for inspecting facilities "that manufacture, process, pack, or hold foods," while the USDA is responsible for inspecting "meat and poultry slaughter and processing establishments."[19] The agreement goes on to outline the responsibilities of the FDA and the USDA moving

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[14] *See* Reiley, *supra* note 3*;* Krstic, *supra* note 3.

[15] Lindsey Pound, *John Dillard*: *Who Will Regulate Lab-Grown Meat?*, DROVERS (Dec. 11, 2018), https://www.drovers.com/news/john-dillard-who-will-regulate-lab-grown-meat [https://perma.cc/R9P8-SAQ6].

[16] Brian Sylvester, *Building the Regulatory Conversation on Cellular Agriculture*, LAW360 (Oct. 30, 2018, 1:42 PM), https://www.law360.com/articles/1096770/building-the-regulatory-conversation-on-cellular-agriculture [https://perma.cc/QMS4-YH8C]; FRANK YIANNAS & MINDY BRASHEARS, FORMAL AGREEMENT BETWEEN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION AND U.S. DEPARTMENT OF AGRICULTURE OFFICE OF FOOD SAFETY 1 (2019) https://www.fsis.usda.gov/wps/wcm/connect/0d2d644a-9a65-43c6-944f-ea598aacdec1/Formal-Agreement-FSIS-FDA.pdf?MOD=AJPERES [https://perma.cc/X3XE-278E] [hereinafter F.S.I.S.].

[17] *See* F.S.I.S., *supra* note 16.

[18] *Id.* Such statutory justification of authority is necessary for the agencies' oversight here, as an agency may not act beyond "the scope of its lawful authority." Allentown Mack Sales & Serv., Inc. v. N.L.R.B., 522 U.S. 359, 374 (1998); *see also* Stark v. Wickard, 321 U.S. 288, 309 (1944) ("When Congress passes an Act empowering administrative agencies to carry on governmental activities, the power of those agencies is circumscribed by the authority granted.").

[19] *See* F.S.I.S., *supra* note 16.

forward.[20] The FDA will: (1) conduct premarket consultations with clean meat producers, including oversight of the collection of tissue and cell lines, and all other necessary materials; (2) inspect and oversee maintenance of cell banks; (3) "[o]versee proliferation and differentiation of cells through the time of harvest"; (4) help coordinate the transfer of harvested cells to the USDA's regulatory oversight; (5) monitor production facilities for compliance with existing FDA requirements; and (6) ensure cell bank and culturing facilities meet FDA standards and that processes protect against adulteration.[21] The USDA will: (1) assist in the transfer of oversight from the FDA of harvested cells; (2) require that facilities harvesting cells cultured from amenable species bear a USDA mark of inspection;[22] (3) inspect facilities involved in culturing cells from amenable species; (4) oversee and enforce labeling requirements of cultured meat products; and (5) enforce appropriate regulation.[23] Both agencies will be responsible for sharing information with one another, and will jointly develop and undertake a framework and operating procedure which will delineate each agency's respective role in the inspection process for lab-grown clean meat.[24] The agencies have also committed to developing joint labeling procedures and will cooperate further as needed.[25]

This arrangement is far from ideal for several reasons. First, prior to this announcement, the FDA and the USDA were vying for control in the industry, and there is no guarantee that they will cooperate now that they have announced a joint regulatory regime.[26] Additionally, the USDA is subject to agency "capture" by the meat industry, meaning that the meat industry is able to leverage its influence to induce the USDA to consistently act in accordance with the industry's goals rather than acting to

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[20] *Id.* at 2–4.

[21] *Id.* at 2. "Adulteration" of food is defined in 21 U.S.C. § 342, which details a number of ways in which a food may become adulterated. These include if the food "bears or contains any poisonous or deleterious substance which may render it injurious to health," is "a new dietary ingredient for which there is inadequate information to provide reasonable assurance" of the food's safety, or if the food "is transported . . . under conditions that are not in compliance" with food safety regulations under the FDCA. 21 U.S.C. §§ 342 (a)(1), (f)(1)(B), (i).

[22] A "mark[] of inspection" is an official USDA mark placed on inspected carcasses and meat food products that indicates that the product has passed official inspection. 9 C.F.R. § 316.9.

[23] *See* F.S.I.S., *supra* note 16, at 3.

[24] *Id.* at 4.

[25] *Id.*

[26] *See* 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 [https://perma.cc/2T6H-GJXY].

protect the public interest.[27] As a result of this capture, the USDA can hardly be counted on to act as a fair and neutral party as it helps to develop this important regulation.[28] Finally, the USDA is designed and mandated to supervise the rearing, slaughter, and butchering of certain animals to produce meat products,[29] but clean meat involves neither animal agriculture nor slaughter. Regulating the labs and manufacturing facilities where clean meat will be cultured, produced, and packaged is outside the scope of the UDSA's mandate; the FDA, given the types of facilities and food products it regulates, is a more appropriate regulatory agency for clean meat. The FDA should assume exclusive regulatory control over the clean meat industry to enable the industry to flourish as the technology further advances.

The FDA, using its power to determine "standard[s] of identity" of food products,[30] should define lab-grown clean meat as a product other than meat, thereby definitively removing clean meat from within the regulatory purview of the USDA and placing the burgeoning clean meat industry squarely and solely under FDA regulation and supervision. The USDA's statutory mandate with respect to meat and poultry is to supervise farms, slaughter, and post-slaughter meat packing,[31] and the Department's authority over meat is limited to only certain segments of the industry.[32] For these reasons, defining lab-grown meat as something other than "meat" would remove it from within the statutory purview of the USDA, which is captured by the meat industry.

This note proceeds as follows. Part I addresses the meat industry's capture of the USDA, and highlights the implications of this capture for the regulation of lab-grown clean meat. Part II explains why regulating clean meat falls outside of the USDA's statutory purview and why it would therefore be inappropriate for the USDA to regulate the lab-grown meat industry. Part III analyzes the FDA's role as the appropriate regulatory agency for clean meat and suggests a method by which the FDA can assume

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[27] Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1340 (2013). The FDA is no less susceptible to capture than the USDA, but the FDA simply does not regulate any comparable industries. Therefore, the FDA does not have a similar stake in obstructing the development and growth of the clean meat industry.

[28] Steve Johnson, *The Politics of Meat*, PBS: FRONTLINE, https://www.pbs.org/wgbh/pages/frontline/shows/meat/politics/ [https://perma.cc/PPJ3-GT8Q].

[29] *See* 21 U.S.C. §§ 603, 606.

[30] 21 U.S.C. § 341. The FDA's standards of identity power gives the agency the authority to define foods and determine their ingredient composition, and to dictate how the foods should be manufactured, labeled, and marketed. Nemphos v. Nestle Waters N. Am., Inc., 775 F.3d 616, 621–22 (4th Cir. 2015).

[31] 21 U.S.C. §§ 601–06.

[32] Supreme Beef Processors, Inc. v. U.S.D.A., 275 F.3d 432, 434 (5th Cir. 2001).

total regulatory control over clean meat. The FDA can use its power to define lab-grown clean meat as a food product other than meat, which would bring clean meat products fully and exclusively within the FDA's regulatory mandate.

I. THE USDA IS "CAPTURED" BY THE TRADITIONAL MEAT INDUSTRY AND SHOULD NOT REGULATE CLEAN MEAT

The traditional meat industry has captured the USDA to such an extent that the Department has elevated the interests of the meat industry over the health and safety of the public. This has led to serious consequences for American consumers who have become sick and even died as a result of the Department's failure to adequately regulate and supervise the meat industry. In addition to these consumer protection concerns, the capture of the USDA casts serious doubt on whether the USDA can be trusted to fairly regulate the burgeoning clean meat industry, which threatens to seriously disrupt the profits of traditional meat producers.

A. Defining and Identifying Capture

"Capture" is a phenomenon particular to government whereby "organized interest groups successfully act to vindicate their goals through government policy at the expense of the public interest."[33] Both elected and unelected officials serving in government bureaucracy can be captured.[34] This problem is particularly acute in certain agency-regulated industries and "[f]or groups that are repeat players before specialized agencies, investments in long-term relationships can have substantial returns in terms of influence, raising capture concerns."[35] When regulatory agencies are influenced by special interest groups to enact or enforce regulations that promote the special interest groups' goals at the expense of the public interest, the phenomenon is more specifically known as "agency capture."[36] Fundamentally, agency capture is the theory that agencies are likely to do the

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[33] *See* Livermore & Revesz, *supra* note 27, at 1340. Capture may initially seem similar to lobbying. "Lobbying" is defined as "addressing or soliciting members of a legislative body for the purpose of influencing their vote" and "has been characterized as an indispensable element of the legislative process, being that of communicating the people's needs and wishes to the legislature." William M. Howard, Annotation, *Validity, Construction, and Application of State and Municipal Enactments Regulating Lobbying and of Lobbying Contracts*, 35 A.L.R. 6th 1 (2008). Capture and lobbying are different in that lobbying does not necessarily result in ends that are contrary to public interest, whereas industry capture results in the elevation of a particular interest group's agenda above the general public interest.

[34] *See* Livermore & Revesz, *supra* note 27, at 1343–44.

[35] *Id.* at 1340.

[36] *Id.* at 1343.

bidding of the industries they are intended to regulate because they have been co-opted by those industries in a variety of ways.[37]

Capture can occur through "lobbying or other influential devices" and results in the replacement of an agency's stated public policy agenda with the agenda of the party that has captured the agency.[38] Agency capture and capture of elected officials often work in tandem, and can be conceptualized as an "iron triangle," in which

> special-interest groups, congressional committees, and agencies exist in stable, mutually beneficial alliances. Under this formulation, interest groups provide members of Congress with campaign contributions and other forms of support in exchange for favorable legislation and agency oversight. Congressional committees provide agencies with their authorizing powers and their budgets in exchange for agency responsiveness to policy demands. Agencies provide interest groups with favorable regulatory treatment in exchange for political support in Congress and perks such as postgovernment jobs.[39]

Interest groups and industries influence agencies in more subtle ways as well, "including the control of information, manipulation of how questions are posed to agencies, and thick, interlocking personal and professional networks that include both agency personnel and outsiders."[40] Agency capture often results in regulation that favors the regulated parties.[41]

There are many forces that drive capture, including the limited nature of an agency's resources, which often causes regulators to rely heavily on industries that they regulate for the information they need to make relevant policy decisions.[42] Additionally, because regulation materially affects industry profits and can involve millions of dollars in industry gains or losses, the stakes are significantly higher for these industries than they are for individual taxpayers, whose tax burden may only change slightly as a result of new or amended regulations.[43]

Another factor driving capture is the nature of the U.S. political system.[44] It is far more difficult and costly to organize a movement of citizens to oppose or support potential regulation

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[37] Dion Casey, *Agency Capture: The USDA's Struggle to Pass Food Safety Regulations*, 7 KAN. J. L. & PUB. POL'Y 142, 142–43 (1997).

[38] Mark C. Niles, *On the Hijacking of Agencies (and Airplanes): The Federal Aviation Administration, "Agency Capture," and Airline Security*, 10 AM. U. J. GENDER, SOC. POL'Y & L. 381, 390 (2002).

[39] *See* Livermore & Revesz, *supra* note 27, at 1343–44.

[40] *Id.* at 1344.

[41] *See* Niles, *supra* note 38, at 401.

[42] *Id.* at 393.

[43] *Id.* at 400.

[44] *Id.* at 393–96.

than it is for a few industry insiders to work directly with elected officials and agency personnel on regulatory issues.[45] Also, regulated industries are "extremely familiar with [an agency's] decision making processes" while most members of the public are not, so these industries are far more capable of influencing agencies as they consider regulation.[46] This information gap is exacerbated by the "revolving door" between regulated industries and the agencies that regulate them.[47] Finally, regulated industries often lobby Congressional committees and subcommittees that oversee the agencies that regulate their activities.[48]

Clean meat technology is still in its infancy.[49] It is essential that the body tasked with developing and implementing regulation of this new industry is able to act independently of the meat industry, which has its own stated interest in influencing the future of clean meat.[50] Unless the United States undergoes a fundamental change in how it regulates lobbyists, agency personnel, and money in politics, the forces driving capture are unlikely to disappear in the near future, and may ultimately negatively influence the growth of the clean meat industry.

B. Regulation Rodeo: How "Big Meat" Has Captured the USDA

The USDA is a quintessential example of an agency that is captured by the industries it is meant to regulate, namely, the meat and poultry industries.[51] There is "ample evidence"[52] of the "powerful" role these industries play in shaping the legislative and

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[45] *Id.* at 394. Industry insiders have existing relationships with legislators and regulators and sophisticated understandings of the relevant issues. Unlike the average citizen, these insiders do not need to be educated on the issues, nor mobilized in great numbers, and, because of their pre-existing relationships in Washington, can more easily bypass gatekeepers in Congress and regulatory agencies to present their case directly to high-level decision-makers. *Id.*

[46] *Id.*

[47] The "revolving door" phenomenon describes both private industry players coming to work within agencies that regulate the industries that formerly employed these players, and agency personnel leaving government roles to work in the industries their former agencies regulated. Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Institutional Design*, 89 TEX. L. REV. 15, 23, 46 (2010).

[48] *See* Casey, *supra* note 37.

[49] Mary Allen, *Clean Meat Production 101*, GOOD FOOD INST. (Oct. 31, 2018), https://www.gfi.org/clean-meat-production-101 [https://perma.cc/VR3C-H5QA].

[50] *See* Petition for U.S. Cattlemen's Ass'n at 1–11, *In re* Beef and Meat Labeling Requirements: To Exclude Products Not Derived Directly From Animals Raised and Slaughtered From the Definition of "Beef" and "Meat," (U.S.D.A. 2018) (No. 18-01), https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/18-01-Petition-US-Cattlement-Association020918.pdf [https://perma.cc/G5Q8-9JE2].

[51] Bruce Friedrich, *When the Regulators Refuse to Regulate: Pervasive USDA Underenforcement of the Humane Slaughter Act*, 104 GEO. L.J. 197, 210 (2015).

[52] *Id.*

regulatory framework that governs the USDA's activities.[53] For several reasons, the meat and poultry industries have been particularly successful in influencing the agenda of the USDA. The industries assert their will through both direct pressure on the Department itself and through influencing lawmakers who craft the regulations governing USDA enforcement. This capture leads to significant consequences for American consumers, who have fallen ill and even died due to inadequate health and safety regulations governing the meat and poultry industries.[54]

The meat and poultry's capture of the USDA is partially due to structural factors relating to the purpose and operation of the agency. For one, the very design of the USDA lends itself easily to capture, as the agency is statutorily obligated to promote meat, dairy, and egg consumption,[55] which leads the USDA to support and further "an agricultural system that has come to promote the production and consumption of certain foods, including meat and dairy, over all others."[56] The USDA is also particularly vulnerable to capture because facilities under USDA inspection usually pay for the inspection service, as well as "grading, certification and verification services" that meat and poultry producers use to market their products.[57] These producers, then, are essentially "the USDA's customers," which creates a conflict of interest as the USDA attempts to regulate them and oversee their operations.[58] This conflict of interest is exacerbated by the significant size and reach of the meat industry.[59]

Additionally, the "revolving-door" between food industry lobbyists and the USDA enables this agency capture.[60] Although lobbyists generally are not allowed to work in agencies they had previously lobbied, the executive branch can issue waivers allowing lobbyists to do just that, and there are now many meat and poultry industry lobbyists working within the USDA who

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[53] *See* Johnson, *supra* note 28.

[54] *See* Friedrich, *supra* note 51.

[55] *See* Marya Torrez, *Meatless Monday: Simple Public Health Suggestion or Extremist Plot?*, 28 J. ENVTL. L. & LITIG. 515, 525 (2013).

[56] *Id.* at 528.

[57] Mateusz Perkowski, *USDA: A Captive Agency?*, CAP. PRESS (Dec. 18, 2014), https://www.capitalpress.com/nation_world/nation/usda-a-captive-agency/article_da1abcd7-fdd3-5dec-86ca-8b87944ee8b0.html [https://perma.cc/W49Q-AVF5].

[58] *Id.*

[59] A 2016 study found that the U.S. meat and poultry industry accounted for 5.6 percent of U.S. gross domestic product, and the industry employs over 5 million people. *The United States Meat Industry at a Glance*, N. AM. MEAT INST., https://www.meatinstitute.org/index.php?ht=d/sp/i/47465/pid/47465 [https://perma.cc/QVV2-92VU].

[60] Alex Kotch, *Revolving Door: Food Industry Lobbyists Swarm USDA to Shape Welfare, Visa Policies*, TYT NETWORK (Mar. 22, 2018), https://legacy.tyt.com/2018/03/22/revolving-door-food-industry-lobbyists-swarm-usda-to-shape-welfare-visa-policies/ [https://perma.cc/XBR6-BWSE].

craft regulation related to the meat industry.[61] This conflict of interest has risen to the top of the agency, as the former Secretary of Agriculture, Sonny Perdue, holds ownership stakes in several large agricultural companies.[62] The close relationships between agribusiness executives and USDA regulators results in regulation that is insufficient and ineffective at protecting the health of U.S. consumers and has led to "tens of millions of sicknesses, hundreds of thousands of hospitalizations, and thousands of deaths every single year."[63]

A significant consequence of this agency capture is that the USDA's inspection body, the FSIS, has ceded much of its supervisory and inspection power to the meat industry itself.[64] For example, "[i]n 1980, the FSIS established a voluntary Total Quality Control (TQC) program, a 'self-monitored production control program' which allowed inspectors to review an establishment's production records, rather than actually inspect its products, to ensure the products met the agency's standards."[65] Soon after these changes were made, the FSIS further delegated inspection authority by "implement[ing] streamlined inspection systems (SIS) in poultry plants with high-speed lines, which shifted responsibility for quality-assuring tasks (such as detecting and removing visible defects) from inspectors to the plants' employees."[66] By 1986, Congress allowed the FSIS to develop a new proposal for inspecting poultry plants, whereby the FSIS would consider a plant's sanitation history in crafting the plant's inspection schedule and inspection procedures.[67] This proposal would have allowed plants with a history of successfully passing previous inspections to operate with less inspection and oversight from the FSIS, in essence granting some facilities the power to largely self-inspect.[68] The proposal was never enacted, though, as "consumer groups and FSIS employees fought it," leading the FSIS to scrap the proposal.[69]

More recently, the FSIS announced that effective December 2, 2019, the agency was rolling out a new procedure for inspecting

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[61] *Id.*

[62] *Id.* Despite his ties to the agricultural industry and his name, Sonny Perdue is not personally related to the family that owns the large poultry producers, Perdue Farms. Press Release, Office of Commc'ns, Governor of Georgia, Perdue Farms Plans Major Expansion in Georgia (July 14, 2005), https://sonnyperdue.georgia.gov/00/press/detail/0,2668,78006749_79688147_93050140,00.html [https://perma.cc/6JDT-8QWS].

[63] *See* Friedrich, *supra* note 51, at 210.

[64] *See* Casey, *supra* note 37, at 144.

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] *Id.*

[69] *Id.*

pork products, called the New Swine Slaughter Inspection System.[70] This optional procedure allows hog slaughter facilities to utilize their own employees, instead of FSIS inspectors, to conduct the preliminary preslaughter and immediate post-slaughter inspections of hogs and carcasses.[71] While USDA inspectors are still present throughout the inspection process, this change will lessen the number of USDA inspectors in pork production plants because plant employees will take over some of the inspection duties previously held by FSIS inspectors.[72] This change was lauded by the pork industry because it will allow these facilities to process carcasses into pork products more quickly. but food and worker safety experts expressed concern that this was, in effect, "privatizing inspections," which could lead to dangerous conditions for workers and potentially unsafe products for consumers.[73]

In addition to influencing the USDA itself, the traditional meat industry also exerts significant pressure on the lawmakers to enact meat-friendly legislation for regulatory agencies, like the USDA, to later enforce, resulting in an "iron triangle," as defined in the preceding Section. For example, in the early 2000s, Tyson Foods, the largest poultry producer in the United States, bought IBP, "the No. 1 meat processor, forming a Goliath in Market share and political power."[74] This gave both the poultry and beef industry reason to oppose legislation designed to regulate the other since, due to the merger, that regulation would affect producers that were now operating in both of the largest sectors of the meat and poultry economy.[75] This consolidation of power within the meat industry is not an outlier, as the top firms in almost every sector of the meat production industry tend to control the majority of that sector's production, and large companies often operate in more than one sector of the industry.[76] This powerful marriage helped squash legislation

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[70] Modernization of Swine Slaughter Inspection, 84 Fed. Reg. 52,300, 52,300 (Oct. 1, 2019).

[71] *Id.*

[72] Dan Charles, *USDA Offers Pork Companies a New Inspection Plan, Despite Opposition*, NPR (Sept. 17, 2019, 4:29 PM), https://www.npr.org/sections/thesalt/2019/09/17/761682926/usda-changes-rules-overseeing-how-pork-is-produced [https://perma.cc/W2P4-TUCS].

[73] *Id.* An increase in the speed at which pigs are slaughtered and processed would lead to more worker injuries, as the speed of the slaughter and processing line is the most significant factor contributing to slaughterhouse worker injury. *See* Israel Cook, *How Fast is Too Fast? OSHA's Regulation of the Meat Industry's Line Speed and the Price Paid by Humans and Animals*, 18 SUSTAINABLE DEV. L. & POL'Y 39, 39 (2017).

[74] *See* Johnson, *supra* note 28.

[75] *See id.*

[76] ANDREW FISHER & SARU JAYARAMAN , BIG HUNGER: THE UNHOLY ALLIANCE BETWEEN CORPORATE AMERICA AND ANTI-HUNGER GROUPS 146 (2017). In 2011 the "top four companies in each sector [of the meat industry] controlled 82 percent of beef slaughter" and 53

that would have made it easier for the USDA to shut down beef processing plants whose *Salmonella* levels tested above acceptable limits.[77] Tyson was heavily involved in encouraging poultry industry players, like the National Chicken Council, to lobby against the legislation.[78] This lobbying led many senators who represented districts with large poultry interests, and who supported the legislation before the beef-poultry producer merger, to become opponents of the legislation in order to protect their constituent poultry producers, who were now also heavily invested in beef production.[79] This episode is a paradigmatic example of an "iron triangle:"[80] Tyson, the National Chicken Council, and other industry players used their considerable resources to influence legislators in their favor as they considered laws that would have broadened the scope of a regulating agency's powers over a regulated industry.

This pattern of industry pressure on legislators and agency capture of the USDA also results in inadequate sanitary regulations which have put the health of the American public at risk.[81] In one instance, regulators proposed a new USDA regulation, in the form of a Hazard Analysis and Critical Control Point (HACCP) System, to reduce the prevalence of *E. Coli* bacteria contamination in meat.[82] The proposed regulation would implement mandatory chilling procedures, antimicrobial treatments and testing of carcasses, and would require facility management to commit to enforcement and goal-setting with respect to pathogen reduction.[83] The American Association of Meat Processors (the Association) "zealously opposed" this new regulation because it would impose significant costs on its member businesses.[84]

The Association and other meat industry groups initiated a campaign of "direct pressure" on both the USDA and elected officials, leading to congressional attempts to dissuade the USDA from going forward with the new system.[85] This campaign ultimately led the USDA to significantly alter the rule so as to lessen its impact on the meat industry.[86] The final rule did not

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percent of poultry slaughter, and several "companies, such as Tyson, Cargill, and Archer Daniels Midland (ADM) have stakes in multiple sectors, controlling vast swaths of the food system." *Id.*

[77] *See* Johnson, *supra* note 28.

[78] *Id.* The National Chicken Council represents almost 95 percent of the chicken sold in the United States. *Id.*

[79] *Id.*

[80] *See* Livermore & Revesz, *supra* note 27, at 1343–44.

[81] *See* Niles, *supra* note 38, at 402.

[82] *Id.*

[83] *See* Casey, *supra* note 37, at 149.

[84] *See* Niles, *supra* note 38, at 402.

[85] *Id.*

[86] *Id.*

require antimicrobial treatments or chilling of carcasses, and required less frequent testing for pathogens than would have been required in the original proposed HACCP plan.[87] Finally, the adopted rule delegated significant authority to plant managers to develop procedures for pathogen reduction.[88] FSIS inspectors would be retained merely to review plant employees' paperwork and inspection records.[89]

As a result of this episode, the USDA was soon "forced to recall more than twenty-five million pounds of meat" that had potentially been contaminated with *E. Coli*.[90] The initial proposed regulation would have significantly increased the chance that inspectors would discover the bacteria during processing.[91] Instead, however, sixteen people fell ill with *E. Coli* food poisoning before the contamination was discovered.[92]

There are numerous other examples of meat industry players having an adverse impact on the USDA's policies; some of these examples verge on the ridiculous, while others are seriously troubling. For example, when the USDA circulated an internal newsletter suggesting that employees participate in Meatless Monday to reduce their environmental impact, the backlash from the animal agriculture industry and members of Congress for "failing in its duty to American agriculture" was so severe that the idea was scrapped two days later.[93] The USDA went on to remove the newsletter from its website and publicly come out against Meatless Monday.[94] An equally incredulous, but significantly more alarming example, is the fact that multiple government scientists have accused the USDA of censoring or modifying research that threatens agriculture industry profits, and of punishing researchers who make such findings.[95] These examples all illustrate the reality that the USDA is beholden to the traditional meat industry, which has an expressed interest in controlling the U.S. meat market, and, therefore, has a strong interest in shaping the regulatory landscape for lab-grown clean meat.

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87 *See* Casey, *supra* note 37, at 153.

88 *Id.* at 154.

89 *Id.*

90 *See* Niles, *supra* note 38, at 402.

91 *Id.*

92 *Id.*

93 *See* Torrez, *supra* note 55, at 515–16.

94 *Id.* at 516.

95 Tim Schwab, *USDA Censoring Anti-Monsanto Science?*, FOOD & WATER WATCH (Mar. 9, 2016), https://www.foodandwaterwatch.org/news/usda-censoring-anti-monsanto-science-0 [https://perma.cc/434P-KKA2].

C. "Hooked" on Traditional Meat: The Meat Industry's Capture of the USDA Will Inevitably Affect the Regulation of Clean Meat

Given the evidence of meat industry capture of the USDA, the industry's response to the development of clean meat must be viewed with an eye towards how meat producers will most likely influence the USDA's regulation of clean meat. The meat industry has expressed concern about the development of lab-grown meat,[96] and the industry's powerful ability to influence USDA policy means that the traditional meat industry has the potential to drastically influence any regulation the USDA develops or attempts to enforce.

Clean meat producers are acutely aware of and concerned with the potential harm to their burgeoning industry should the meat industry-controlled USDA assume total regulatory authority over them. Many in the clean meat industry fear that their lack of leverage within the USDA, compared with the significant influence of the meat industry on the Department, would lead to regulations that would force clean meat to compete with traditional meat at an unfair disadvantage.[97] These new industry producers have a real and legitimate fear that existing USDA meat regulations would also inhibit research and development in the nascent industry.[98] Finally, they fear that traditional meat producers would leverage their considerable influence over the USDA to pressure the Department to find ways to inhibit the growth of the lab-grown meat industry.[99]

These fears from new clean meat producers are well-founded. For example, the United States Cattlemen's Association (USCA) is on record as attempting to obstruct the development and marketing of clean meat as a viable alternative to traditionally sourced meat products.[100] "In February 2018, the U.S. Cattlemen's Association [] filed a Petition for Rulemaking to the USDA arguing that lab-grown meat should not be labeled as 'meat.'"[101] The

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[96] Taylor A. Mayhall, *The Meat of the Matter: Regulating a Laboratory-Grown Alternative*, 74 FOOD & DRUG L.J. 151, 167 (2019).

[97] Dan Murphy & Joann Alumbaugh, *Murphy: Setting a Trap for Alt-Meat?*, PORK (Apr. 16, 2018), https://www.porkbusiness.com/news/industry/murphy-setting-trap-alt-meat [https://perma.cc/379V-4L6H].

[98] 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 [https://perma.cc/4H5D-4WU9].

[99] *See id.*

[100] *See* Mayhall, *supra* note 96, at 167.

[101] *Id.* A Petition for Rulemaking is the formal procedure whereby a party may submit "a written request to issue, amend, or repeal a regulation administered by FSIS." 9 C.F.R. § 392.2.

petition, supposedly motivated by an interest "to eliminate the likelihood of confusion and to better inform consumers," asks the USDA to limit the use of the terms "beef" and "meat" to "product[s] from cattle born, raised, and harvested in the traditional manner."[102] The petition targets plant and insect sourced imitation meat products, like the Impossible Burger, in addition to lab-grown clean meat.[103] Another industry player, the National Cattlemen's Beef Association (NCBA), "listed 'fake meat' as one of the top five issues the organization planned to tackle in 2018, as the group's leadership vowed to 'protect our industry and consumers from fake meat and misleading labels.'"[104]

In light of the meat industry's strong antipathy towards the development of alternatives to traditionally raised and slaughtered meat, attempts by the industry to influence the regulation of clean meat companies are highly suspect. Yet, this is precisely what has happened. In 2018, the NCBA, which just that year named tackling the issue of "fake meat" a top priority,[105] wrote a letter to the Acting Deputy Undersecretary for Food Safety urging the USDA to assume regulatory authority over lab-grown meat.[106] The letter specifically urged the USDA to "assert jurisdiction over foods consisting of, isolated from or produced from cell culture or tissue culture derived from livestock and poultry animals or their parts."[107]

In addition to the danger that USDA oversight poses to the growth of the clean meat industry, this oversight implicates many serious consumer safety concerns.[108] For example, the Centers for Disease Control and Prevention (CDC) recently opened an investigation into a meat industry connected, drug-resistant *Salmonella* illness outbreak which, over nine months, sickened over 250 people across the United States, sent at least sixty people to the hospital, and led to two deaths.[109] Unlike *E. Coli* and *Listeria,* the FSIS does not consider *Salmonella,* which "causes more than [one] million foodborne illnesses every year and is responsible for more hospitalizations and deaths than any

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[102] *See* U.S. Cattlemen's Ass'n, *supra* note 50, at 2.

[103] *Id.*; *see* Mayhall, *supra* note 96, at 167.

[104] *See* Murphy & Alumbaugh, *supra* note 97.

[105] *Id.*

[106] *Id.*

[107] *Id.*

[108] *See* Press Release, Consumer Fed'n of Am., Foodborne Illness Investigation Exposes Weakness in Meat and Poultry Inspection System (Aug. 22, 2019), https://consumerfed.org/press_release/foodborne-illness-investigation-exposes-weakness-in-meat-and-poultry-inspection-system/ [https://perma.cc/675V-WLP8]; PEW CHARITABLE TRS., WEAKNESSES IN FSIS'S SALMONELLA REGULATION 4 (2013), https://www.pewtrusts.org/-/media/legacy/uploadedfiles/phg/content_level_pages/reports/fsischickenoutbreakreportv6pdf.pdf [https://perma.cc/4URF-3YMF].

[109] *See* Consumer Fed'n of Am., *supra* note 108.

other type of bacterium or virus found in food" to be an "adulterant" under the agency's regulatory framework.[110] Despite the FSIS's detection of the particular strain and other closely related strains of *Salmonella* at several meat and poultry processing facilities, current FSIS regulations do not require producers to recall the beef harboring those pathogens.[111] This interpretation of the FSIS's power (or lack of power) was upheld in *Supreme Beef Processors, Inc. v. U.S. Department of Agriculture*, in which the Fifth Circuit held that *Salmonella* was not an "adulterant" under the relevant provisions of the FMIA,[112] and the FSIS could not, therefore, close facilities whose meat products registered high levels of *Salmonella* in FSIS tests.[113]

Despite calls by consumer advocates for regulation that would more quickly remove *Salmonella*-contaminated meat from the market, the agency continues to require multiple types of repetitive evidence to determine whether a meat product is linked to an illness outbreak.[114] This leads to long delays in the removal of affected products, even when evidence clearly implicates a source for the outbreak.[115] Given the FSIS's limited and "narrow mandate" in this respect,[116] the FSIS would be constrained as to how it could protect consumers should similar pathogens find their way into lab-grown meat. This is true even if the traditional meat industry is able to influence the USDA to overregulate the nascent clean meat industry to inhibit its growth, as some clean meat producers fear.[117] The USDA, through the FSIS, has shown that it is simply unable and unwilling to adequately protect consumers from foodborne pathogens, so even if the Department imposes strict regulations on clean meat, these regulations would not likely include the types of effective health and safety regulations advocates have repeatedly called for.

Finally, large meat companies, like Tyson Foods, have themselves invested in clean meat producers, which increases the

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110 *See* PEW CHARITABLE TRS., *supra* note 108.

111 *See id.*; *see also* Consumer Fed'n of Am., *supra* note 108. The FSIS only requires such action if there exists "epidemiological, microbiological, and trace back evidence" to link the *Salmonella* strain detected at a facility to the strain causing a current outbreak. Consumer advocates pressed the FSIS to implement stricter regulation regarding foods contaminated with *Salmonella*, but the FSIS declined to do so. *Id.*

112 The court reasoned that, since *Salmonella* is present in a "substantial proportion of meat and poultry products," the presence of the pathogen could not be *per se* evidence of adulteration. Supreme Beef Processors, Inc. v. U.S. Dep't of Agric., 275 F.3d 432, 438–40 (5th Cir. 2001).

113 *Id.* at 440–41.

114 *See* Consumer Fed'n of Am., *supra* note 108.

115 *Id.*

116 *Id.*

117 *See* Garfield, *supra* note 98.

danger to consumers of exclusive USDA oversight of the clean meat industry.[118] Given the history of these companies' resistance to amending or augmenting USDA regulation in the interest of consumer safety, their investment in "clean meat" has the potential to influence the USDA towards regulation of that industry in ways that would do little to protect consumers. Additionally, the industry's capture of the USDA could lead to a situation in which USDA regulation of clean meat benefits existing large producers, like Tyson, to the exclusion of smaller clean meat companies without an existing relationship with the USDA.

In sum, the fact that the USDA has been captured by traditional slaughtered meat interests means it would be highly problematic for it to regulate clean meat, given traditional meat interests' strong campaign to hinder the growth of the clean meat industry and given the USDA's poor track record in protecting the public from unsafe food products.

II. CLEAN MEAT DOES NOT FIT WITHIN THE USDA'S MANDATE BECAUSE ITS OVERSIGHT OF THE CLEAN MEAT INDUSTRY IS NOT STATUTORILY APPROPRIATE

Not only is the USDA captured by the traditional meat and poultry industries, which has negative implications for the nascent clean meat industry, but USDA oversight of the clean meat industry is also inappropriate because it goes beyond the statutory purview of the Department. The USDA's statutory purpose with respect to meat and poultry is to supervise farms, slaughter, and post-slaughter meat packing.[119] The USDA does not regulate all meat products, and the Department's statutory authority is limited to only certain segments of the meat industry.[120] The Department regulates these industry segments by promulgating and enforcing rules regarding animal rearing, slaughtering, and processing of animal carcasses.[121] The production of clean meat, which involves culturing cells in a lab,[122] does not, therefore, fall under the USDA's umbrella.

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[118] Alisa Odenheimer, *Tyson Foods Makes Another Investment in Lab-Grown Meat*, BLOOMBERG (May 2, 2018, 9:05 AM), https://www.bloomberg.com/news/articles/2018-05-02/u-s-food-giant-tyson-makes-first-investment-in-israel [https://perma.cc/KTT4-4F5K].

[119] 21 U.S.C. §§ 601–06.

[120] *See* Supreme Beef Processors, Inc. v. U.S. Dep't of Agric., 275 F.3d 432, 434 (5th Cir. 2001); 21 U.S.C. §§ 451, 601(e), (j), (w).

[121] 21 U.S.C. §§ 603, 606.

[122] *See* Allen, *supra* note 49.

A. A Brief History of the USDA's Role in Meat and Poultry Slaughter

The USDA's role in supervising animal agriculture and meat production is over one hundred years old.[123] Congress first delegated supervisory authority over meat exports to the USDA in 1890 and extended the USDA's mandate one year later to cover "ante- and postmortem inspection of livestock slaughtered for meat meant for U.S. distribution."[124] In 1906, Congress passed the FMIA, which "set sanitary standards for slaughter and processing plants and required USDA inspection of every cattle, hog, sheep, and goat carcass" and required the continuous presence of USDA inspectors in all meat manufacturing facilities.[125] The FMIA was passed "in response to unsanitary conditions in the nation's meat packing industry."[126] In 1957, Congress expanded the USDA's role yet again with the passage of the PPIA, which "required the USDA to inspect all poultry carcasses intended for interstate commerce."[127] Finally, in 1967 and 1968, Congress passed the Wholesome Meat Act (WMA) and the Wholesome Poultry Products Act (WPPA), respectively, which, among other things, "gave the USDA control over more aspects of the meat and poultry industries (including storage, transportation, and retail) and more enforcement options (including withdrawal of inspection and detention of suspect carcasses)."[128]

B. Spotlight on Slaughter: The Current Mandate of the USDA

The Secretary of Agriculture is empowered to effectuate the USDA's statutory mandate under the congressional acts that enable USDA oversight of the meat and poultry industry.[129] The Secretary of Agriculture is also "specifically required by Congress to promote and develop markets for meat, dairy, and other animal products."[130] Additionally, the USDA is required to protect consumer health by ensuring meat is wholesome, unadulterated, correctly packaged and not mislabeled or misbranded.[131]

The agency has statutory authority under the FMIA to regulate certain segments of the meat industry through the

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123 *See* Casey, *supra* note 37, at 143.
124 *Id.*
125 *Id.*
126 Munsell v. U.S. Dep't of Agric., 509 F.3d 572, 575 (D.C. Cir. 2007).
127 *See* Casey, *supra* note 37, at 144.
128 *Id.*
129 21 U.S.C. §§ 451, 602.
130 *See* Torrez, *supra* note 55, at 525.
131 21 U.S.C. § 602.

FSIS,[132] which allows the Secretary of Agriculture to set rules for the slaughtering, packing, and processing of meat that will eventually be sold as "meat food products."[133] The FMIA serves the dual purpose of "ensur[ing] both the safety of meat and the humane handling of animals."[134] It authorizes the FSIS inspection procedure, which "begins with an 'ante-mortem' examination of each animal brought to a slaughterhouse."[135] The FMIA only grants the USDA regulatory power over "amenable species" such as beef, pork, goat, and catfish, and not over poultry, seafood, or game meat.[136] Congress granted the USDA, through the FSIS, statutory authority to regulate poultry with the 1957 passage of the PPIA.[137] Finally, the USDA's mandate also requires it to maintain and increase the profits of the meat industry, and warns that unsafe or mislabeled meat products may have significant negative economic effects on the market for meat and poultry.[138]

21 U.S.C. § 603 grants the Secretary of Agriculture power to appoint and delegate inspectors who will inspect animals before slaughter, and inspect the carcasses of those animals after slaughter to ensure the animals carry no visible diseases.[139] Additionally, 21 U.S.C. § 606 grants the Secretary of Agriculture and appointed inspectors power to inspect and label meat food products for consumption, and grants unfettered access to inspect any meat producing facility.[140] Finally, 21 U.S.C. § 608 gives the Secretary of Agriculture power to inspect meatpacking establishments.[141]

Animal rearing, slaughtering, and processing are integral to the USDA's mandate, as the FMIA itself contemplates only meat products derived "wholly or in part, from the carcass or parts of any cattle, sheep, swine, and goat. These animals, defined as 'livestock' in the regulations, must be slaughtered and processed under Federal inspection, and the meat food products must be inspected and passed for human consumption."[142] The FMIA's inspection protocol requires inspectors to "be present at all times during

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[132] *See* 21 U.S.C. §§ 601–08.

[133] Supreme Beef Processors, Inc. v. U.S. Dep't of Agric., 275 F.3d 432, 434 (5th Cir. 2001).

[134] Nat'l Meat Ass'n v. Harris, 565 U.S. 452, 455 (2012).

[135] *Id.* at 456.

[136] 21 U.S.C. §§ 601(e), (w).

[137] 21 U.S.C. § 451.

[138] 21 U.S.C. § 602.

[139] 21 U.S.C. §§ 603–04.

[140] 21 U.S.C. § 606.

[141] 21 U.S.C. § 608.

[142] UNITED STATES DEP'T OF AGRIC., SUMMARY OF FEDERAL INSPECTION REQUIREMENTS FOR MEAT PRODUCTS 2 (2015), https://www.fsis.usda.gov/wps/wcm/connect/e6658a9c-915f-4283-beaf-a827b35e906a/Fed-Food-Inspect-Requirements.pdf?MOD=AJPERES [https://perma.cc/4MEY-CDGK].

livestock slaughter operations and for at least part of each shift during which there is further processing of meat products."[143] In essence, the USDA's statutory authority extends to regulation of rearing, slaughtering, and processing activity for meat from amenable species, and extends no further.

C. "Lab to Table": Why Regulating Clean Meat Falls Outside the USDA's Statutory Purview

The regulation of clean meat falls outside of the USDA's statutory purview. There are several reasons why the many laws and regulations that govern the conduct and operations of the USDA and the FSIS cannot be expanded or interpreted to govern the regulation of clean meat. First, the USDA, through the FSIS, lacks the proper statutory infrastructure to oversee clean meat. Second, the public health considerations related to traditional meat do not apply to clean meat. Finally, the USDA regulates agriculture, which is not involved in clean meat production. The following section will discuss each of these issues in turn.

1. The USDA Lacks Proper Statutory Infrastructure to Oversee Clean Meat

The USDA regulates slaughter and meatpacking facilities.[144] Clean meat is produced in a laboratory and does not involve slaughter or the handling of animal carcasses, and only briefly involves interaction with livestock at the time when the cells to be cultured are initially harvested.[145] Therefore, production of clean meat looks very little like the production that the USDA is designed to regulate. Additionally, some traditional meat industry players themselves have cautioned against classifying clean meat as meat.[146] Taking this perspective to its logical conclusion would place lab-grown meat squarely outside the mandate of the USDA and the FSIS.[147]

The USDA also does not currently have the infrastructure to support regulation and supervision of the clean meat industry. For one, clean meat is grown from stem cells, which can be harvested from the body of a live animal, so the process of creating clean meat does not necessitate animal

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[143] *Id.*

[144] 21 U.S.C. §§ 601–06.

[145] *See* Allen, *supra* note 49.

[146] *See, e.g.*, U.S. Cattlemen's Ass'n, *supra* note 50.

[147] For a discussion of why the USDA may not act outside its statutory mandate, see *supra* note 18.

slaughter.[148] The primary regulatory focuses of the FMIA and PPIA, on the other hand, are the premortem inspection of livestock[149] and poultry,[150] the slaughter of livestock,[151] and antemortem inspection of carcasses which will be processed into meat food products.[152] "Carcass" is defined as "[a]ll parts, including viscera, of any *slaughtered* livestock."[153] Clean meat involves neither slaughter nor carcasses as statutorily defined, so the FMIA and PPIA's frameworks governing inspections do not envision the type of oversight necessary to ensure the safety and wholesomeness of clean meat. This will become increasingly true as clean meat technology advances—while the stem cells from which clean meat is cultured are currently derived from animal muscle cells, researchers predict they will soon be able to culture meat-producing cells from other sources, namely, feathers and hair follicles.[154] This further distances clean meat from the traditionally sourced—that source being animal carcasses—meat and poultry contemplated by the FMIA and PPIA. Therefore, in order for the USDA to supervise and inspect the production of clean meat, the FSIS would need to completely overhaul its current regulatory language to include meat derived from animals that were not slaughtered in the traditional manner and to include meat derived from animals that were not slaughtered at all.[155] This further indicates that FSIS is not

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[148] Christopher J. Bryant, *Culture, Meat, and Cultured Meat*, 98 J. ANIMAL SCI, 1, 1 (2020).

[149] *See* 21 U.S.C. § 603(a).

[150] *See* 21 U.S.C. § 455(a).

[151] *See* 21 U.S.C. § 603(b).

[152] *See* 21 U.S.C. §§ 604–05; *see also* 21 U.S.C. § 455 for analogous regulations governing post mortem inspection of slaughtered poultry.

[153] 9 C.F.R. § 301.2(p) (emphasis added).

[154] *See* Murphy & Alumbaugh, *supra* note 97.

[155] *See* Mayhall, *supra* note 96, at 166. In his article, Mayhall argues that adjustments need only be made to a handful of the regulations governing FSIS inspection of meat food products. A cursory glance at the regulations and policies promulgated by the USDA, however, shows that significant changes would need to be made to allow for FSIS oversight of clean meat. For example, almost every section in the chapter of statutes governing USDA regulatory oversight of the meat industry references either "slaughter" or "carcass." *See, e.g.*, 21 U.S.C. § 601(e) ("The term 'animal food manufacturer' means any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses . . . . "); 21 U.S.C. § 601(j) ("The term 'meat food product' means any product . . . which is made . . . from any meat or other portion of the carcass [of livestock]"); 21 U.S.C. § 603 ("Examination of [A]nimals [P]rior to [S]laughter; [U]se of [H]umane [M]ethods"); 21 U.S.C. § 604 ("Post [M]ortem [E]xamination of [C]arcasses . . . . "); 21 U.S.C. § 609 ("Examination of [A]nimals and [F]ood [P]roducts [T]hereof, [S]laughtered and [P]repared [D]uring [N]ightime"); 21 U.S.C. § 621 ("The Secretary shall appoint . . . inspectors to make examination and inspection . . . of all carcasses and parts thereof . . . . "). Similarly, 21 U.S.C. Ch. 10, which governs poultry inspection, is rife with references to poultry carcasses and poultry slaughter. *See generally* 21 U.S.C. §§ 451–71. Additionally, the Code of Federal Regulations defines meat in relation to livestock bodies, carcasses, and slaughter. 9 C.F.R. §§ 301.2(p), (rr), (uu) (defining

designed to cover foods outside its narrow scope of slaughtered animal sourced meat products.

The types of facilities intended for USDA oversight also indicate that the USDA is not the appropriate agency to regulate lab-grown meat. The FSIS's inspection program operates exclusively within meat and poultry slaughter operations. For example, the FMIA states that the Secretary of Agriculture is to direct inspectors to oversee "all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which amenable species are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary . . . ."[156] The FMIA defines "animal food manufacturer" as "any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines."[157] A "meat food product" under the FMIA is

> any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as 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.[158]

The fact that all of these regulations involve animal carcasses, which play no role in the production of clean meat, shows that the USDA is ill-equipped for this new method of meat production.

In the definition of meat food product cited above, the USDA is mandated to ensure that no adulteration occurs in meat products. A meat food product can become "adulterated" when it is

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"carcass" as any part of "slaughtered livestock"; defining "meat" as the skeletal muscles or certain organs of livestock; and "meat food product" as "[a]ny article capable of use as human food which is made . . . from any meat or other portion of the carcass" of certain species). The USDA's website indicates that the FSIS inspects products derived from the "carcass or parts" of livestock and notes that animals "defined as 'livestock' in the regulations [] must be slaughtered and processed under Federal inspection." *Inspection of Meat Products*, U.S. DEP'T OF AGRIC., https://www.fsis.usda.gov/inspection/inspection-programs/inspection-meat-products. [https://perma.cc/MF2R-RVEP]. These are just some of the instances where statutes or regulations would have to be changed to reflect FSIS oversight of clean meat, indicating that more is needed than just a minor adjustment or tweak to the language in a few statutes.

156 21 U.S.C. § 608.

157 21 U.S.C. § 601(e).

158 21 U.S.C. § 601(j).

wholly or partially sourced from an animal that died in a manner other than slaughter.[159] Troublingly, the USDA's statutory language could potentially define lab-grown meat as adulterated merely because its source was not "slaughtered" in a traditional meat processing facility pursuant to USDA regulation.

The FMIA and the PPIA regulate federally and state-inspected meat and poultry plants, as well as foreign plants, whose meat is inspected upon import into the United States.[160] A lab where meat is developed in vitro is not a "similar establishment" under this definition because these labs do not engage in the slaughter of amenable species.[161] Additionally, even if a lab was the type of facility contemplated by the statute, inspectors are only directed to inspect "amenable species, and the food products thereof, slaughtered and prepared in the establishments hereinbefore described for the purposes of commerce to be made."[162] Again, clean meat does not fall within those proscribed bounds because handling livestock and poultry either alive or as meat is not essential to the production of clean meat beyond the initial harvesting of cells to culture.[163]

Finally, the meat industry itself has given conflicting statements regarding whether clean meat can properly be classified as meat by the USDA. In some instances, the beef industry has argued that clean meat is not in line with USDA's statutory definitions of beef.[164] For example, in its 2018 letter to the USDA, the NCBA wrote that "lab-grown meat is not congruent with traditional beef and should not be permitted to be marketed as beef."[165] In that same letter, though, the NCBA argues that cell-cultured meat falls "within the statutory definition of a meat food products [sic]" because they are derived from parts of animal carcasses.[166] Notwithstanding the inaccuracy of that statement about the source of cell-based meat,[167] this letter indicates a belief by beef industry players that they can have their proverbial cake

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159 21 U.S.C. § 601(m).

160 Dailey v. Veneman, No. 01-3146, 2002 WL 31780191, at *1 (6th Cir. Dec. 3, 2002).

161 *See* Allen, *supra* note 49.

162 21 U.S.C. § 609.

163 *See* Allen, *supra* note 49.

164 Letter from Kevin Kester, President, Nat'l Cattlemen's Beef Ass'n, to Carmen M. Rottenberg, Acting Deputy Under Sec'y for Food Safety, Food Safety and Inspection Serv. 1–3 (Apr. 10, 2018).

165 *Id.* at 2.

166 *Id.* at 2.

167 "Carcass" is statutorily defined as parts from slaughtered livestock. 9 C.F.R. § 301.2(p). Cells from which cell cultured meat is developed are not necessarily harvested from slaughtered animals. *See* Bryant, *supra* note 148, at 1. Therefore, cell-based meat does not fall within the statutory definition of a "meat food product" because the cells are not sourced from animal carcasses. *See* 9 C.F.R. § 301.2(uu).

(or burger) and eat it too—they can insist that cell based meat should not be labeled and marketed to consumers as *real* meat, while still insisting that the USDA, over which they hold significant sway,[168] maintain regulatory oversight of the industry.

2. Traditional Meat's Public Health Considerations Do Not Apply to Clean Meat

In addition to promoting the consumption of meat food products, the FMIA and the PPIA share a purpose to protect the public health of consumers and to guard against adulteration or misbranding of animal carcasses.[169] Meat sourced from carcasses must be carefully inspected as it can easily become unsafe through contact with "contaminants" like "fecal material, urine, bile, hair, dirt, or foreign matter."[170] Additionally, the FSIS promulgates rules regarding premortem inspection of livestock and poultry to ensure the animals are free from disease[171] and postmortem inspection to check for pathogens, the presence of animal parts not fit for consumption, and other contaminants.[172] Clean meat, though, is not sourced from an animal carcass and, therefore, there is no risk of the types of contamination contemplated by the FSIS regulations because clean meat does not come into contact with animal carcasses at all when it is produced.[173] Since clean meat does not carry the same public health risks as traditional meat, the USDA acts outside of its statutory authority when it oversees the production of clean meat.

The USDA's authority is also very narrowly constrained to slaughter and processing operations.[174] Although pathogens are most likely to spread at livestock feedlots and stockyards, the USDA does not have authority to test for pathogens outside slaughter facilities, leaving the USDA unable to "protect humans" beyond the slaughterhouse.[175] Since producing clean meat does not, by design, require a slaughterhouse, the USDA has very little power to protect consumer health and safety in the production of clean meat.

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168 *See supra* Sections I.B.–C.
169 Kenney v. Glickman, 96 F.3d 1118, 1120–21 (8th Cir. 1996).
170 9 C.F.R. § 310.18(a).
171 9 C.F.R. §§ 309.1, 381.70.
172 9 C.F.R. §§ 310.1–.25, 381.76–.94.
173 *See* Bryant, *supra* note 148, at 1.
174 *See* Consumer Fed'n of Am., *supra* note 108.
175 *Id.*

3. The USDA Regulates Agriculture, Which is Not Involved in Clean Meat Production

The USDA not only governs animal slaughter and meat inspection, but the Department also oversees and regulates livestock and poultry farming as well.[176] The FSIS, which operates under the umbrella of the USDA, therefore conceptualizes meat though this traditional agricultural lens; this is evidenced by the fact that the agency refers to the "farm-to-table" path traveled by the meat it inspects.[177] Additionally, the FSIS's stated responsibilities include implementing certain provisions of The Agricultural Marketing Act,[178] which covers the distribution and marketing of "agricultural products."[179] Finally, the types of animals included on the USDA's list of "amenable species"[180] further indicates that the USDA is primarily concerned with governing *agriculture*; the fact that the only fish that the USDA does regulate—catfish[181]—are traditionally farmed, adds credence to that claim.

In the case of clean meat, though, there is no farm or agricultural element. Clean meat is produced by "invitro cultivation of animal cells."[182] These cells are developed into meat entirely within a lab setting,[183] so there is no agriculture or farm involved in the production of clean meat products. Clean meat production does not implicate the types of issues related to live animal rearing or agriculture that are traditionally governed by the USDA.[184]

The USDA is therefore not prepared through the FSIS to inspect food safety of clean meat, where carcasses are not involved. Also, since clean meat production does not involve slaughter and carcass processing at all,[185] there is simply no reason to involve the USDA in regulating clean meat.

The USDA is not the appropriate regulatory body for clean meat. For one, the USDA's statutory structure does not lend itself to regulating clean meat, as it is mainly concerned with animal rearing, transport, slaughter, and processing. Additionally, the

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176 *Animal Policy and Regulatory Issues*, U.S. DEP'T OF AGRIC., https://www.ers.usda.gov/topics/animal-products/animal-policy-regulatory-issues/ [https://perma.cc/4NFS-9Q8A].

177 9 C.F.R. § 300.3(c)(1); *Memoranda of Understanding (MOU)*, U.S. DEP'T OF AGRIC., MEMORANDA OF UNDERSTANDING (MOU), https://www.fsis.usda.gov/about-fsis/food-safety-agency-partners/memoranda-understanding-mou [https://perma.cc/37N9-KAMH].

178 9 C.F.R. § 300.2(6).

179 7 U.S.C. § 1621.

180 21 U.S.C. §§ 601(e), (w).

181 21 U.S.C. § 601(w)(2) (the definition of "amenable species" includes Siluriformes, which is the scientific name for catfish).

182 *See* Banis, *supra* note 8.

183 *See id.*

184 *See Animal Policy & Regulatory Issues*, *supra* note 176; 9 C.F.R. § 300.2(6); 21 U.S.C. §§ 601(e), (w).

185 *See* Allen, *supra* note 49.

public health considerations involved with traditional meat production do not apply to clean meat, since clean meat involves neither raising live animals nor handling their carcasses after slaughter. Finally, the USDA is mainly concerned with agriculture, and because clean meat does not involve agriculture, it does not fall within the purview of the Department.

III. THE FDA IS THE PROPER REGULATOR FOR LAB-GROWN MEAT

The FDA's purpose, and the Agency's statutory powers to accomplish that purpose, are far more suitable to regulate clean meat than those of the USDA. Additionally, the FDA is not captured by the meat industry. This is not to say that the FDA is any less subject to agency capture in general than the USDA, but the crucial issue is that the FDA is not *currently* captured by the meat industry, unlike the USDA.[186] Nor is it likely to be captured by meat and poultry interests, which have already signaled their intention to obstruct the development of the clean meat industry, because, unlike the USDA, the FDA does not regulate those industries.[187] There is, therefore, no relationship between the meat industry and the FDA that would facilitate the type of agency capture that has taken place at the USDA.

This Part will proceed in two sections. Section A discusses the FDA's purposes, which include protecting public health and safety, regulating new food ingredients, and overseeing food facilities, including labs involved in food production. Section B then discusses the FDA's powers to bring clean meat under its regulatory umbrella and why it should do so.

A. The Purposes and Mandate of the FDA

The FDA's mission to protect public health and safety, and to provide oversight of new food technology and food facilities, including laboratories,[188] make the FDA better suited to regulate clean meat. The FDA derives its statutory power from the FDCA, 21 U.S.C. § 341, which, in part, grants the FDA authority to regulate food safety.[189] As part of the FDA's core mission to protect the public from unsafe or unsanitary food products, the Agency

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[186] *See supra* Sections I.B.–C.
[187] *See supra* Sections I.B.–C.
[188] 21 U.S.C. §§ 341, 350d(a)(1), 350k.
[189] 21 U.S.C. § 341.

ensures that foods are properly labeled.[190] The FDA has "broad" authority to regulate foods, including "food products," "blood products," "tissue products," "cellular and gene therapy products,"[191] and "[a]ll food shipped in interstate commerce."[192] As such, the FDA "regulates over 80 percent of the U.S. food supply, including dairy, seafood, produce, [and] packaged foods[.]"[193] The FDA also regulates "meat from exotic animals," and "fish, shellfish, and all seafood—except farmed catfish."[194] Finally, the FDA regulates food facilities and requires that "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered[.]"[195] The FDA's purpose to protect the health and safety of consumers, and its ability to do so through its grant of broad regulatory power, makes the FDA the superior agency to regulate clean meat.

The FDA is also tasked with regulating food additives and new food technology. The Agency's enabling statute defines "food" as: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[196] Crucially, the FDA also regulates "food additive[s]," which is defined 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 (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . .[197]

Congress granted the FDA this power in 1958 by enacting the Food Additives Amendment.[198] The core element of the amendment was a requirement that the FDA approve any new chemical additive as safe before that additive can be used in food

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[190] Nemphos v. Nestle Waters N. Am., Inc., 775 F.3d 616, 619 (4th Cir. 2015) (citing 21 U.S.C. § 393(b)(2)(A)).

[191] *What Does the FDA Regulate?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate [https://perma.cc/YY7V-HWGV].

[192] Smith v. Wisconsin Dep't of Agric., 23 F.3d 1134, 1135 (7th Cir. 1994).

[193] Daniele Galarza, *USDA vs. FDA: What's the Difference?*, EATER (Mar. 24, 2017, 1:32 PM), https://www.eater.com/2017/3/24/15041686/fda-usda-difference-regulation [https://perma.cc/M8HX-E6NW].

[194] *Id.*

[195] 21 U.S.C. § 350d(a)(1).

[196] 21 U.S.C. § 321(f).

[197] 21 U.S.C. § 321(s).

[198] *FDA's Approach to the GRAS Provision: A History of Processes*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/generally-recognized-safe-gras/fdas-approach-gras-provision-history-processes [https://perma.cc/7DXY-85H3].

production, unless the food additive is "generally recognized as safe."[199] The FDA is, then, clearly tasked with overseeing emerging food products and technology, and supervising the development of clean meat and its related technology fits squarely within this mandate.

The FDA also oversees food facilities. Under the FDCA, a food facility subject to the FDA's registration requirements includes "any factory, warehouse, or establishment . . . that manufactures, processes, packs, or holds food. Such term does not include farms" under its definition of a "facility" subject to its registration requirements.[200] The parties in charge of facilities which fall under the statute are required to "evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility" and "identify and implement" preventative measures to ensure food safety.[201] This requirement involves an identification of "biological, chemical, physical, and radiological hazards, natural toxins . . . drug residues . . . parasites, allergens, and unapproved food and color additives."[202]

The FDA's mandate is more concerned with the types of facilities and risks associated with clean meat and it is therefore a better agency to regulate the development of this new food technology. Unlike the USDA's regulatory scheme, which is almost exclusively concerned with farms, slaughterhouses, and butchering facilities, the FDA's regulatory scheme is a truer fit for the types of facilities likely to develop and manufacture clean meat, namely, labs and manufacturing facilities. To that point, the FDCA specifically discusses regulations relating to labs in the food industry.[203] Section 350k of the Act provides for an accreditation process for labs intended to test food.[204] This section also provides "model laboratory standards,"[205] and regulations on testing procedures to take place in these labs.[206] While the labs contemplated in this section are primarily labs intended for testing food during and after processing, this section provides a

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[199] *Id.*

[200] 21 U.S.C. § 350d(c)(1). The USDA, on the other hand, oversees facilities "in which amenable species are slaughtered and the meat and meat food products thereof are prepared for commerce." 21 U.S.C. § 608. These facilities include slaughterhouses, and "meat canning, salting, packing, rendering, or similar establishments." *Id.*

[201] 21 U.S.C. § 350g(a).

[202] 21 U.S.C. § 350g(b)(1)(A).

[203] *See* 21 U.S.C. § 350k.

[204] *See id.* In contrast, the food-industry labs regulated by the USDA are largely concerned with testing meat for disease, rather than developing new food technology. *See, e.g.*, *Laboratory Information and Services*, U.S. DEP'T OF AGRIC., https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services [https://perma.cc/BW32-X9DK].

[205] *See* 21 U.S.C. § 350k(a)(6).

[206] *See* 21 U.S.C. § 350k(b).

blueprint for how the FDA could regulate labs where cells are cultured into clean meat.[207] As the USDA is, again, primarily concerned with slaughterhouses and farms,[208] neither the FMIA nor the PPIA contain a similar section, so the FDA is, therefore, better prepared by its nature to regulate the facilities where clean meat will be developed. Additionally, unlike the USDA's concern with contaminants like bodily fluids, dirt,[209] and bacterial pathogens, like *Salmonella*, which spread in slaughterhouses through cross-contamination,[210] the types of contaminants the FDA is concerned with—"biological . . . and radiological hazards . . . residues . . . and additives"[211]—are more likely to be found in labs and manufacturing facilities, which are the types of facilities in which clean meat is produced.[212]

Not only is the FDA a better fit statutorily speaking, the FDA also has history and experience regulating new food technology. For instance, the FDA governs the regulation of genetically modified plant products, which includes plants created with tissue culture techniques.[213] The FDA's long history of regulating these products indicates that the FDA is familiar with modified foods and biotechnology in a way that the USDA simply is not, and the FDA is therefore better prepared to handle analogous questions and issues that relate to the development of clean meat that may arise as the technology for clean meat is developed.

This power to regulate these products is exercised through the "Plant Biotechnology Consultation Program," which was created in the 1990s to work with developers creating genetically engineered (GE) plant varieties to make sure these new plant products are safe for consumers.[214] Through this program, the FDA "has completed consultations on more than 180 genetically engineered plant varieties."[215] Pursuant to this power, the "FDA has ample authority under the act's food safety provisions to regulate and ensure the safety of foods derived

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[207] *Id.*

[208] *See supra* Part II.

[209] *See* 9 C.F.R. § 310.18.

[210] *See* PEW CHARITABLE TRS., *supra* note 108, at 8.

[211] 21 U.S.C. § 350g(b)(1)(A).

[212] *See* Allen, *supra* note 49.

[213] *Statement of Policy: Foods Derived from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statement-policy-foods-derived-new-plant-varieties [https://perma.cc/5FVR-BQVQ].

[214] *Consultation Programs on Food from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties [https://perma.cc/9DF4-RSHK].

[215] *Understanding New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-new-plant-varieties/understanding-new-plant-varieties [https://perma.cc/77QG-64EV].

from new plant varieties . . . . This includes authority to require, where necessary, a premarket safety review by FDA prior to marketing of the food."[216] Additionally, the FDA regularly consults with developers of GE plant varieties "about the safety of foods from their new varieties prior to them entering the marketplace."[217] Finally, the FDA publishes information about the new GE plant variety for the public to access.[218]

In addition to the fact that the FDA already has a robust history of and mechanism for regulating new food technologies, any meats or proteins sourced from species not explicitly listed in the FMIA and the PPIA, called "nonamenable species," are already regulated by the FDA rather than the USDA.[219] For example, the FDA regulates seafood[220] and meat sourced from game animals.[221] Therefore, and it is apparent that the USDA does not have a monopoly on meat inspection and regulation and, since the FDA already knows how to inspect and regulate many types of meat, the Agency could naturally assume oversight over clean meat.

Regulating the burgeoning clean meat industry falls within the purposes of the FDA. The FDA exists to ensure that food, and especially new food ingredients and technologies, are safe for the general public. The FDA has ample experience overseeing the development of these new foods and technologies and in regulating the facilities and laboratories in which these new foods are produced. Finally, the FDA is quite familiar with regulating meat products, as it already regulates many meat products that are not within the USDA's statutory power to regulate. For these reasons, the FDA is absolutely the proper agency to regulate the production of new clean meat products and to oversee the technology and facilities that develop clean meat.

B. The FDA Has Significant Statutory Power to Regulate Clean Meat and Should Exercise Its Existing Powers to Assume Exclusive Oversight of Clean Meat

Unlike the USDA, the FDA already has significant power to regulate clean meat production and to ensure the health and safety

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[216] *See Statement of Policy: Foods Derived from New Plant Varieties*, *supra* note 213.

[217] *See Understanding New Plant Varieties*, *supra* note 215.

[218] *See Consultation Programs on Food from New Plant Varieties*, *supra* note 214.

[219] *See* UNITED STATES DEP'T OF AGRIC., *supra* note 142, at 2; *see also* Denise Amann, *Harvesting Wild Game*, 5 SMALL PLANT NEWS 1, 2 https://ucanr.edu/sites/CESonoma AgOmbuds/files/296051.pdf [https://perma.cc/X9D5-BPPF]; *Non-Amenable Species*, U. CAL. AGRIC. & NAT. RESOURCES, https://ucanr.edu/sites/CESonomaAgOmbuds/Selling_Meat/Non-Amenable/ [https://perma.cc/ZH8C-4B5Z].

[220] 21 C.F.R. §§ 123, 1240.

[221] *See Non-Amenable Species*, *supra* note 219.

of clean meat as it emerges on the market. First, from a consumer protection perspective, FDA oversight would better protect the health and safety of consumers as compared to USDA oversight. The FSIS does not have the power to issue mandatory recalls.[222] The FDA, though, can initiate mandatory recalls of contaminated food as a result of congressional amendments to the food safety law in 2011.[223] The FDA, therefore, has more power to protect public health with respect to clean meat development.

Additionally, the FDA has the authority to regulate "[n]ew dietary ingredients," which lends further support to the conclusion that it is the superior agency to oversee the production of clean meat.[224] As part of this authority, the FDA is responsible for overseeing any manufacturer or distributor of these "new" ingredients to ensure the products are safe before they are introduced to consumers in the market.[225] The FDA defines "[n]ew dietary ingredient" as an "ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994."[226] While meat obviously has a long history as a food ingredient, meat derived from stem cells or other cellular components certainly did not exist in the United States before 1994[227] and can reasonably be considered a "new dietary ingredient," placing clean meat further within the FDA's regulatory mandate.

Additionally, in pursuing its fundamental goal of combating misbranding, the FDA is empowered to "promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity[.]"[228] This power gives the Agency the exclusive and "far-reaching" powers to define foods and to determine which ingredient(s) ought to make up those particular foods.[229] This power also allows the FDA to regulate how foods are labeled and marketed to ensure consumers are not misled about a food's

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[222] *See* PEW CHARITABLE TRS., *supra* note 108, at 10.

[223] *Id.*

[224] 21 U.S.C. § 350b.

[225] *Id.*

[226] 21 U.S.C. §§ 350b, b(d). Examples of food products the FDA has recently considered as "[n]ew dietary ingredients" include chicken collagen derived from freeze-dried chicken bone powder, Omega-7 fish oil, Korean Red Ginseng Extract, and Cannabidiol (CBD). *Submitted 75-Day Premarket Notifications for New Dietary Ingredients*, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2021), https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/submitted-75-day-premarket-notifications-new-dietary-ingredients [https://perma.cc/UX7A-QB8F].

[227] *World's First Lab-Grown Burger is Eaten in London*, BBC (Aug. 5, 2013) https://www.bbc.com/news/science-environment-23576143 [https://perma.cc/3XU5-J3R9].

[228] 21 U.S.C. § 341.

[229] Nemphos v. Nestle Waters N. Am., Inc., 775 F.3d 616, 621 (4th Cir. 2015) (quoting 62 Cases v. United States, 340 U.S. 593, 598 (1951)).

composition or nutritional value.[230] Finally, the standards of identity power allows the FDA to set standards for how particular foods may be manufactured.[231] Consequently, producers are prohibited from adding ingredients—even wholesome and safe ingredients—to foods if those ingredients are not within the FDA's standard of identity for that particular food product.[232] Congress clearly intended for the FDA to define new foods especially if they are purporting to be similar or imitation versions of existing, familiar foods,[233] reinforcing the position that the FDA is the appropriate regulatory body for clean meat.

The FDA should, therefore, use its regulatory power to ensure lab-grown meat is never statutorily defined as "meat." This reflects the reality that "meat" is defined to have come from particular animal carcasses.[234] Lab-grown clean meat does not come from any carcass, and regulating clean meat is in line with the clear congressional intent for the FDA to define and oversee the development of new food products.[235] Defining clean meat this way will fully establish the FDA as the proper and exclusive regulator for lab-grown meat. Doing so is important for the future of clean meat technology because, as the technology for growing cell-cultured proteins becomes more advanced, the range of proteins replicated through this process may very well extend to foods already regulated by the FDA. For example, the company BlueNalu has already coined the term "cellular aquaculture" to describe its process to use cell culture technology to produce lab-grown seafood products from fish cells.[236] It is not hard to imagine a lab or facility in which beef cells are cultured alongside salmon cells, and, in such a case there is no logical reason why the beef cells' product should be inspected by one agency, while the salmon cells' product is inspected by another.

If the FDA defines clean meat as a product other than "meat," there may be push-back from clean meat producers, who will argue that their product, is, in fact, meat, and should be defined as

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[230] *Id.*

[231] *Id.* at 622. For example, the FDA standard of identity for milk defines milk as "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows." 21 C.F.R. § 131.110(a). The FDA standard of identity for mayonnaise defines mayonnaise as "the emulsified semisolid food prepared from vegetable oil(s), one or both of the acidifying ingredients specified [later in] this section, and one or more of the egg yolk-containing ingredients specified [later in] this section." 21 C.F.R. § 169.140.

[232] Fed. Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218, 232 (1943).

[233] *Id.*

[234] 21 U.S.C. § 601(j).

[235] *See Quaker Oats Co.*, 318 U.S. at 232.

[236] *Seafood Without the Sea: Will Lab-Grown Fish Hook Consumers?*, NPR (May 5, 2019, 7:00 AM) https://www.npr.org/sections/thesalt/2019/05/05/720041152/seafood-without-the-sea-will-lab-grown-fish-hook-consumers [https://perma.cc/F5QY-K83H].

such. Ultimately, though, this approach is the best way to ensure that clean meat is pulled entirely out from under the regulatory thumb of the USDA. Exclusive FDA regulation of the clean meat industry, for all the reasons previously discussed, is ultimately a better outcome for the nascent clean meat industry, and clean meat producers should, therefore, advocate for this outcome.[237]

CONCLUSION

Clean meat is an exciting development in food technology. The growth of the clean meat industry will allow consumers to purchase, cook, and eat protein sources that fully replicate traditionally sourced meats without the negative environmental, humanitarian, and animal welfare concerns prevalent in the current meat industry.[238] Given the promising potential and the as-yet "unknowns" with respect to consumer safety inherent in the development of this nascent industry, regulation must be carefully tailored to protect the needs of consumers while allowing the industry to grow. Placing clean meat under even the partial regulatory oversight of the USDA will not accomplish those ends. The USDA is "captured" by the traditional meat industry to such an extent that it consistently fails to protect consumer safety.[239] Because of this capture, the USDA cannot be trusted to be a fair and neutral party in helping to craft and enforce regulations for the clean meat industry, an industry in which some traditional meat interests are highly invested, and others have vehemently opposed.[240] Finally, the USDA's mandate and structure is primarily concerned with the supervision of live animals and slaughterhouses, and the Department is simply unprepared to oversee the harvesting and culturing of cells into clean meat.[241] Given these concerns, the FDA should assume complete regulatory control over clean meat. The FDA can do so by using its power to develop standards of identity for food products, which it can subsequently use to define clean meat and bring the product under its regulatory umbrella.[242]

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[237] Additionally, this was an outcome for which the beef industry lobbied extensively. *See* U.S. Cattlemen's Ass'n, *supra* note 50 (urging the USDA not to use the term "meat" to describe lab grown meat); Murphy & Alumbaugh, *supra* note 97 (describing lab grown meat as "fake meat").

[238] *See* Banis, *supra* note 8.

[239] *See supra* Part I.

[240] *See* Krstic, *Vegan Proteins*, *supra* note 7; Morris, *supra* note 10; Reiley, *supra* note 3; Watson, *supra* note 12.

[241] *See supra* Part II.

[242] *See supra* Part III.B.

Almost a century ago, Winston Churchill predicted that we could "escape the absurdity of growing a whole" animal just to satiate our desire for meat.[243] Thanks to the development of clean meat, we are on the verge of realizing Churchill's vision. Unfortunately, USDA participation in regulating the nascent clean meat industry threatens to stifle the industry's growth and endangers the health and safety of the American consumer. By assuming exclusive regulatory control over clean meat, the FDA can help ensure that the clean meat industry is not only safe, but that it is allowed to flourish, bringing us one step closer to a world covered in "[p]arks and gardens" rather than "pastures and plowed fields."[244]

Zoe A. Bernstein[†]

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[243] *See* Churchill, *supra* note 1, at 397.

[244] *Id.*

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