ARTICLE

IT’S JUST “MEAT”: TRAVERSING LAB-GROWN MEAT LABELING AND SAFETY REGULATIONS TO COMBAT FOOD SCARCITY AND CLIMATE CHANGE

KEVIN SFORZA*

Lab-grown, cell-based meat produced ex vivo may dramatically transform the diets of carnivorous climate change critics and benefit the environment on a global scale. Like its plant-based meat predecessors, cell-based meat aims to satisfy the population’s insatiable hunger for meat but with one key difference: cell-based meat has the potential to be identical to animal-based meat at the cellular and molecular level. While plant-based meat uses soy, wheat, and coconut to mimic a burger’s taste and mouthfeel, cell-based meat may provide the exact same animal-like product meat-eaters love without exploiting slaughtered animals or macronutrient replacement. Cell-based meat is poised to provide consumers with the meat they crave without any of the devastating environmental effects caused by traditional agriculture.

While cell-based meat may revolutionize the global food economy and environment, regulators are faced with unprecedented issues of how to regulate the new meat. To preserve their own place on grocery store shelves, livestock and dairy producers have argued to restrict regulations and labeling of cell-based meat. However, under a joint regulatory framework announced in 2018, the FDA and USDA should regulate and label cell-based meat just as they have with animal-based meat. In short, cell-based meat is just “meat.” This Article argues that current regulations label products solely based on the product’s safety and

* J.D., Ph.D. Thank you first and foremost to Deepti Kulkarni, Partner at Sidley Austin, LLP, for your patience, guidance, and willingness to share your insight and expertise on this fascinating subject. Thank you also to Professors Rena Steinzor and Frank Palumbo for inspiring my passion for food and drug law. Thank you to my husband, Anthony May, for your optimism, understanding, and support. This Article is dedicated to my friends, Audrey Rossi and Andrew Phillips, who have inspired me to leave the world better than I found it. I miss you Audrey. Thank you for butchering my last name.
composition, but not by the processes used to create the product. Under this framework, cell-based meat products should be labeled using the common or usual names because the final product is not materially different from the product derived from slaughtered animal. This Article also offers a proposed outline for cell-based meat manufacturers and regulators to adapt for future evaluations under FDA’s premarket consultation process.

INTRODUCTION ....................................................................................... 246

I. THE EXISTING REGULATORY FRAMEWORK FOR MEAT STANDARDS OF IDENTITY ................................................................ 252
   A. Judicial Scrutiny Permits the Sale of Novel Food Products that Are at Least Equivalent to Traditional Food Standards ............ 253
   B. FDA and USDA Standards of Identity Do Not Require Live Animal Sources for Accurate Product Labeling........................... 254
   C. Labeling Requirements Have Long Focused on Food Safety and Composition, Not Food Production Processes .................... 256
   D. The 2016 National Bioengineered Food Disclosure Standard May Shift the Focus of Labeling Towards Production Processes ............ 257

II. INTEREST GROUPS PRESSURED THE FDA AND USDA TO REEVALUATE THE CURRENT REGULATORY FRAMEWORK ......... 260
   A. The U.S. Cattlemen’s Association Petition—The Lightning Rod that Sparked the Cell-Based Meat Labeling Debate ...................... 260
   B. Responses to the USCA Petition Urge the USDA to Label Cell-Based Meat as “Meat” ............................................... 262
   C. Pressure to Evaluate and Coordinate the FDA and USDA Regulatory Frameworks for Cell-Based Meat .................................. 264
   D. FDA and USDA Announce a Joint Framework to Regulate Cell-Based Meat .......................................................... 266

III. HOW SHOULD THE FDA AND USDA REGULATE AND LABEL CELL-BASED MEAT UNDER THE JOINT FRAMEWORK? ............ 267
   A. Premarket Regulation by FDA and a Proposed Premarket Consultation Process Outline for Cell-Based Meat ....................... 269
   B. Current USDA Regulatory Schemes Permit Cell-Based Meat to Be Labeled Using the Common or Usual Name .................... 273

CONCLUSION ........................................................................................... 276

APPENDIX ................................................................................................. 277

INTRODUCTION

According to the 2018 Fourth National Climate Assessment, “Projected changes in precipitation, coupled with rising extreme temperatures before mid-century, will reduce [U.S.] Midwest agricultural productivity to levels of the
1980s without major technological advances.”¹ Contravening this projected decimation of agricultural productivity, experts estimate that by 2050 the world’s population will “grow by one-third, reaching between 9 billion and 10 billion people.”² Projections show that feeding a population of 9.1 billion people in 2050 would require raising overall food production by roughly seventy percent.³ With agriculture and animal grazing already monopolizing about forty percent of the planet’s available land surface,⁴ there is little room for agricultural expansion even in an optimal climate. To meet the needs of an expanding population consuming limited available resources, the issue is not whether diets will change, but how and when diets will change.

The link between the human population and food production has inspired many studies on securing food for all people, focusing on “raising productivity, facilitating access to markets, reducing waste, or changing diets.”⁵ According to Dr. Susan Mayne, the Director of the Food and Drug Administration’s (FDA) Center for Food Safety and Applied Nutrition, “feeding the growing global population” is a “critical challenge,” and

¹. Jim Angel et al., Midwest, in 2 Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment 873 (David Reidmiller et al. eds., U.S. Glob. Change Rsch. Program rev. ed. 2019), https://nca2018.globalchange.gov/downloads/NCA4_Ch21_Midwest_Full.pdf. The U.S. Global Change Research Program (USGCRP) is comprised of thirteen U.S. federal departments and agencies “that carry out research and support the Nation’s response to global change.” USGCRP, 1 Climate Science Special Report: Fourth National Climate Assessment 1 n.2 (D.J. Wuebbles et al. eds. 2017), https://science2017.globalchange.gov/downloads/CSR_FrontMatter.pdf (“The USGCRP is overseen by the Subcommittee on Global Change Research (SGCR) of the National Science and Technology Council’s Committee on Environment, Natural Resources, and Sustainability (CENRS), which in turn is overseen by the White House Office of Science and Technology Policy (OSTP). The agencies within USGCRP are the Department of Agriculture, the Department of Commerce (NOAA), the Department of Defense, the Department of Energy, the Department of Health and Human Services, the Department of the Interior, the Department of State, the Department of Transportation, the Environmental Protection Agency, the National Aeronautics and Space Administration, the National Science Foundation, the Smithsonian Institution, and the U.S. Agency for International Development.”).


recognizing the “potential for innovation” including “new approaches for delivering protein.”

Recognizing the growing market need for animal-free meat alternatives, companies like Impossible Foods Inc. (Impossible Foods) and Beyond Meat Inc. (Beyond Meat) introduced plant-based protein products to U.S. markets. To get its product to “bleed” like a cattle-raised beef burger, Impossible Foods produced a patented method to produce a heme protein from soy, also known as soy leghemoglobin. With its growing patent portfolio, Impossible Foods is poised to potentially corner the market for products using its unique heme production process.

As of June 2019, manufacturers of plant-based meat products claimed their products were on sale at nearly 20,000 restaurants across the United States. Many restaurants were eager to add plant-based meat products to their menus “to remain relevant.” With popularity of plant-based burgers soaring in the United States, Burger King announced its plan to introduce the Impossible Burger in European markets. Plant-based meat producers are also currently looking to expand into foreign markets, like China, while


11. Id. (statement of Jamie Richardson, Vice President for Corporate Relations at White Castle System, Inc.).

startups in those markets aim to leverage their own knowledge of local tastes to gain an edge over U.S. companies.\textsuperscript{13}

However, plant-based meat producers face challenges throughout the United States. On August 28, 2018, Missouri was the first state to enact a law prohibiting producers from “misrepresenting a product as meat that is not derived from harvested production livestock or poultry.”\textsuperscript{14} At least twenty-five states introduced similar bills, and some passed in Mississippi, Oklahoma, Arkansas, Montana, South Carolina, North Dakota, and South Dakota.\textsuperscript{15} While unsuccessful in Missouri,\textsuperscript{16} Arkansas granted Tofurky’s motion for a preliminary injunction challenging the restrictive state statute.\textsuperscript{17} In that case, Judge Kristine G. Baker from the Eastern District of Arkansas found Tofurky was likely to succeed on the merits of its First Amendment claim against the State.\textsuperscript{18} Importantly, Judge Baker found that Tofurky’s additional labeling (“plant-based,” “veggie,” etc.) on the front of its products reduced any potential consumer confusion when considering the label as a whole.\textsuperscript{19} In line with the reasoning in the Arkansas decision, the Plant-Based Food Association (PBFA), a trade association comprised of over 300 members,\textsuperscript{20} released labeling standards for meat alternatives to create consistency across this emerging food

\begin{footnotes}
\footnote{16. The Good Food Institute and Tofurky filed for a preliminary injunction and challenged the Missouri statute on First Amendment, Due Process, and Dormant Commerce Clause grounds. Complaint for Declarative and Injunctive Relief at 2, Turtle Island Foods, SPC v. Richardson, 425 F. Supp. 3d 1131 (W.D. Mo. 2018) (No. 2:18-cv-04173). However, the court denied relief. Turtle Island Foods, 425 F. Supp. 3d at 1141 (No. 2:18-cv-04173).}
\footnote{18. Id. at 11–12.}
\end{footnotes}
sector.\textsuperscript{21} PBFA’s voluntary standards allow for references to animal meat the plant-based products represent, as long as the meat reference is accompanied with “[q]ualifier” language like “Plant-based,” “Vegan,” or “Meatless.”\textsuperscript{22}

Despite its booming popularity among some consumers, many omnivores have issues with the first wave of plant-based meat products. For instance, some consumers avoid the plant-based protein because it is derived from known allergens like soy and wheat and because the final product lacks in taste when compared to real beef.\textsuperscript{23} To get others to try the product, some consumers even admitted to tricking their loved ones by sneaking it into meals.\textsuperscript{24} On April Fools’ Day in 2019, one Burger King in St. Louis, Missouri went so far as to serve Impossible Burgers to unsuspecting customers.\textsuperscript{25} As one strategist states, among “flexitarians, those actively working to reduce meat consumption in their diet, . . . there is a greater need to produce meat alternatives that closely match the eating experience of beef, chicken and other animal[-]based products.”\textsuperscript{26}

Indeed, the United States and the rest of the world will one day rely on cell-based meat and other technology to feed the population.\textsuperscript{27} Recently at a U.S. Department of Agriculture (USDA) and FDA Joint Public Meeting, USDA Secretary Sonny Perdue stated, “[there are] going to be nine billion hungry souls and that means we must feed them, wherever they are, by whatever means are available and necessary . . . . [W]e are talking about a ‘whatever it takes and all of the above’ technology, including new technology like cell cultured meat.”\textsuperscript{28}

\begin{footnotes}
\item[22.] Id. at ¶ 3.
\item[23.] See Julia B. Olayanju, \textit{Plant-based Meat Alternatives: Perspectives on Consumer Demands and Future Directions}, \textsc{Forbes} (July 30, 2019, 12:07 PM), https://www.forbes.com/sites/juliabolanajanju/2019/07/30/plant-based-meat-alternatives-perspectives-on-consumer-demands-and-future-directions/#324970af6daa (“The issue I see currently is that there are many ‘first wave’ bands whose products don’t meet the needs of consumers (lacking taste and mostly based on proteins from known allergens) and newer products that are primarily focused on beef.”).
\item[25.] Id.
\item[26.] Olayanju, supra note 23 (statement of Julie Emsing Mann, Global Protein Strategy and Innovation, Plant Based Proteins at Ingredion).
\item[27.] See supra text accompanying notes 1–4.
\item[28.] Transcript for USDA-FDA Joint Public Meeting on the Use of Cell Culture
\end{footnotes}
To satisfy consumers’ palates, cultured cell-based meat may solve our population’s increasing protein demands. Memphis Meats recently announced it raised $161 million to bring its cell-based meat, poultry, and seafood products to customers. Other start-ups—including Mosa Meat, SuperMeat, and Finless Foods—are also developing lab-grown beef, pork, poultry, and seafood. Cell-based meat is grown \textit{ex vivo}\footnote{Ex \textit{vivo} means that which takes place “outside of the living body.” \textit{Ex vivo}, NAT’L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/ex-vivo.} in a lab using cultured cells derived from animal sources. This “clean meat” requires “less land, water, and energy to produce than meat that comes from live animals,” and “there are no slaughterhouses involved.”

As cell-based meat gets closer to the market, many animal and dairy farmers are calling for stricter regulations. Just as they fought against plant-based meat alternatives, some cattle and dairy producers and farmers are leading the charge against cell-based meat. The United States Cattlemen’s

\begin{itemize}
  \item \textit{See Daphne Ewing-Chow, Is Cultured Meat the Answer to the World’s Meat Problem?, FORBES [June 20, 2019, 2:08 PM], https://www.forbes.com/sites/daphneewingchow/2019/06/20/is-cultured-meat-the-answer-to-the-worlds-meat-problem/#41243b474468 (discussing how the global demand for meat or meat-like products is growing).}
  \item \textit{Ex \textit{vivo} means that which takes place “outside of the living body.”}
\end{itemize}
Association (USCA) is leading the charge against all animal-free meet, and it filed a petition with the USDA to restrict labeling of meat to only animal-slaughtered products. With the recent announcement that the FDA and USDA will share regulatory authority over cell-based meat, many question how the agencies will implement their joint plan.

This Article analyzes current regulations and argues that cell-based meat and poultry products should be labeled under their common or usual names so long as the composition of the final product matches the composition and identity standards of animal-based meat. Part I examines the existing regulatory framework for meat. Part II discusses pressures leading up to the FDA and USDA’s announcement of a joint regulatory framework for cell-based meat. Part III synthesizes a solution under the joint framework for the FDA’s regulation of premarket production of cell-based meat and the USDA’s regulation of labeling the final product. Finally, this Article concludes that cell-based meat should be regulated and labeled as meat. Additionally, Appendix A offers a proposed outline for cell-based meat manufacturers and regulators to adapt for future evaluations under FDA’s premarket consultation process. The proposed outline includes only components from GRAS notifications, and will likely need to be supplemented with components from food additive submissions.

I. THE EXISTING REGULATORY FRAMEWORK FOR MEAT STANDARDS OF IDENTITY

The “FDA is the primary federal agency responsible for ensuring the safety of commercial food and food additives, except meat and poultry products.” The USDA regulates most meat and poultry products and works closely with the FDA on food safety matters. The Federal Food Drug and Cosmetic Act (FDCA) requires new food producers to ensure that food products are safe and in compliance with law. This Section explores the existing FDA and USDA regulatory frameworks around standards for identifying and labeling meat. Part IA briefly discusses how early twentieth century case law enabled future identity regulations to be upheld. Part IB details the current FDA and USDA standards of identifying “food” and “meat.” Part IC discusses how, up until recently, food labeling focused on

37. See infra note 99; see also infra Part II.A.
38. See infra Appendix A.
40. See id.
41. See id.
safety rather than the food production processes. Part LD examines how the 2016 National Bioengineered Food Disclosure Standard marked a narrow shift in labeling policy by calling for disclosure of the production processes for genetically modified organisms (GMOs).

A. Judicial Scrutiny Permits the Sale of Novel Food Products that Are at Least Equivalent to Traditional Food Standards

A court’s role is typically limited to understanding the constitutional limits on agency activities. To ensure food safety, the Supreme Court upheld laws prohibiting the sale of impure food to prevent injury or deception. In United States v. Carolene Products Co., the Court upheld the application of the Filled Milk Act to prevent the sale of adulterated milk. The adulterated filled milk contained nonfat milk and coconut oil, but was not fortified with vitamins to make it as nutritious as real milk. The successor case, Carolene Products Co. v. United States, and its progeny marked the dismantling of economic substantive due process used to strike down regulatory schemes. These early cases established the level of scrutiny for adulterated food that is of lesser quality than its traditional counterpart.

However, some courts may invoke stricter scrutiny where regulations are used to protect traditional food products against new products made through modern food technologies. In Milnot Co. v. Richardson, the Illinois district court scrutinized court application of the Filled Milk Act to the dairy product Milnot. Like existing products in the market, Milnot was a dairy product

42. 304 U.S. 144 (1938).
44. Id. at 148–49 & n.2 (“The use of filled milk as a dietary substitute for pure milk results, especially in the case of children, in undernourishment, and induces diseases which attend malnutrition.”).
45. 323 U.S. 18 (1944).
46. Bradley P. Jacob, Back to Basics: Constitutional Meaning and “Tradition”, 39 TEX. TECH. L. REV. 261, 278–79 (2007) (footnote omitted) (“The Court first stated a strong rational basis presumption in favor of the constitutionality of legislation ‘affecting ordinary commercial transactions.’ Then, in the famous footnote four, the Court identified those types of statutes that it would more strictly evaluate to determine whether they violate substantive due process standards.”).
48. See generally id. at 223–24 (addressing the constitutionality of the Filled Milk Act’s application to Milnot in comparison to the Act’s application to other similar products resembling milk).
comprised of fat-free milk and vegetable oil fortified with vitamins A and D. The court refused to use the Filled Milk Act to prohibit the interstate distribution of Milnot because there were already dairy products on the market that were very similar to Milnot’s “composition, appearance, and use . . . .” The court reasoned that Milnot’s similar composition worked against any argument that Milnot caused confusion in the market.

In line with the Milnot reasoning, critics closely scrutinize judicial doctrines that protect established producers from competition. Regulating cell-based meat products will likely pose similar challenges because the technology is new and nontraditional; and the products are poised to compete with similarly composed, animal-based products.

B. FDA and USDA Standards of Identity Do Not Require Live Animal Sources for Accurate Product Labeling

The FDA promulgates standards of identity to establish the composition of some foods, including mandatory and optional ingredients. Furthermore, the FDA fixes the amounts or relative proportions of each ingredient or a specific method of manufacture for different kinds of food. The standards of identity are meant to resemble “recipes” for specific foods. Section 401 of the FDCA provides the statutory authority for the FDA to promulgate

---

50. Id. at 222–23.
51. Id. at 224.
52. See id. (“No useful purpose is served by listing such products here by name or otherwise, or by discussing the dairy market conditions and dangers of confusion which led to the passage and judicial upholding of the Filled Milk Act many years ago.”).
53. See Jerry L. Mashaw, Constitutional Deregulation: Notes Toward a Public, Public Law, 54 Tul. L. Rev. 849, 872 (1980) (“Although consumers and oppressed dealers are the purported beneficiaries, there is no role for the former in enforcement . . . . Whatever the legislature wanted to do, what it in fact did was provide a means for delaying, and perhaps thwarting, new competition.”).
54. See 21 U.S.C. § 341 (setting forth the duties of the FDA Secretary in regulating food through labeling and other measures.)
55. See generally id. § 342 (noting circumstances where changes in amount of ingredient added to a particular food, or changes to manufacturing practices for a certain food, will cause a food product to become adulterated).
standards of identity for food via regulation. However, the USDA, not the FDA, regulates the standards for meat and beef.

Under the Federal Meat Inspection Act (FMIA), the Food Safety and Inspection Service (FSIS) under the USDA is primarily responsible for regulating food labeling for meat producers. Meat is exempt from the FDCA provisions only to the extent that the FMIA applies. The FMIA states that meat or meat food products shall be “misbranded” if its “labeling is false or misleading in any particular.” Products are considered mislabeled where, among other things, they are “offered for sale under the name of another food,” are “an imitation of another food, unless [the] label bears, in type of uniform size and prominence, the word ‘imitation’ and immediately thereafter, the name of the food imitated,” or “purport to be or [are] represented as a food for which a definition and standard of identity or composition has been prescribed by regulations” without conforming to the applicable definition.

FMIA defines the term “meat food product” as “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.” USDA regulations further define specific beef products, including “ground beef.”

---

57. 21 U.S.C. § 341 (“Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container.”).


60. 21 U.S.C. § 601(n)(1).

61. Id. § 601(n)(2)–(3), (7).

62. Id. § 601(j) (emphasis added). Because cell-based meat is derived from animal meat, it would likely fit squarely within this definition for “meat food product.” See infra note 118 and accompanying text.

63. 9 C.F.R. § 319.15(a) (2020) (“‘Chopped Beef’ or ‘Ground Beef’ shall consist of chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat in such, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. When beef cheek meat (trimmed beef cheeks) is used in the preparation of chopped or ground beef, the amount of such cheek meat shall be limited to 25 percent; and if in excess of natural proportions, its presence shall be declared on the label, in the ingredient statement required by § 317.2 of this subchapter, if any, and otherwise contiguous to the name of the product”).
“hamburger,”64 “beef patties,”65 and “fabricated steak.”66 Specifically, the definition of “fabricated steak” allows for formed and frozen steak products in line with the FSIS regulation.67 Furthermore, while the USDA does not define “beef” or “beef products” in its FSIS regulations, it does define such terms in its Agricultural Marketing Service (AMS) regulations. AMS sets out definitions for “meat,”68 and “poultry product.”69 None of these regulations require “meat” or related products to be directly sourced from live animals.

C. Labeling Requirements Have Long Focused on Food Safety and Composition, Not Food Production Processes

Since 1992, the United States has traditionally operated its food labeling regulatory scheme primarily to address food safety concerns rather than its production process.70 Until recently, the United States did not have a food

64. Id. § 319.15(b) (“‘Hamburger’ shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasoning, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of hamburger only in accordance with the conditions prescribed in paragraph (a) of this section.”).

65. Id. § 319.15(c) (“‘Beef Patties’ shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings. Binders or extenders, Mechanically Separated (Species) used in accordance with § 319.6, and/or partially defatted beef fatty tissue may be used without added water or with added water only in amounts such that the product characteristics are essentially that of a meat pattie”).

66. Id. § 319.15(d) (“Fabricated beef steaks, veal steaks, beef and veal steaks, or veal and beef steaks, and similar products, . . . shall be prepared by comminuting and forming the product from fresh and/or frozen meat, with or without added fat, of the species indicated on the label. Such products shall not contain more than 30 percent fat and shall not contain added water or extenders. Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of fabricated beef steaks only in accordance with the conditions prescribed in paragraph (a) of this section.”).

67. Id.

68. 9 C.F.R. § 301.2 (2020) (“The part of the muscle of any cattle, sheep, swine, or goats which is skeletal . . . . with or without the accompanying and overlying fat, and the portions of bone . . . .”).

69. 9 C.F.R. § 381.1 (2020) (“[A]ny poultry carcass or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof . . . .”). “Carcass” is also defined. 9 C.F.R. § 301.2 (“All parts, including viscera, of any slaughtered livestock”).

70. Neil D. Hamilton, Legal Issues Shaping Society’s Acceptance of Biotechnology and Genetically Modified Organisms, 6 DRAKE J. AGRIC. L. 81, 96–97 (2001) (footnote omitted) (“[The United States’] food labeling system is only designed to address food safety concerns, no matter how the food was developed.” (citing Statement of Policy: Foods Derived from New Plant Varieties, 57
labeling system “based on a consumer’s right-to-know.” Thus, most labeling policies require some evidence of a safety risk, rather than mere reasoning or speculation, to mandate additional labeling. While food producers may voluntarily provide safety information through labeling, the food industry generally declines to do so.

Even the courts have agreed that additional labeling notifying consumers of the production process should not be required if the process is determined to be safe. In *International Dairy Foods Ass’n v. Amestoy*, the U.S. Court of Appeals for the Second Circuit struck down a Vermont statute that required cattle farmers to involuntarily disclose to consumers that the cattle were treated with a growth hormone. The court reasoned that consumer desire to know which products were derived from hormone-treated herds was insufficient to compel farmers to label their products as such. “Absent, however, some indication that this information bears on a reasonable concern for human health or safety[,] . . . the manufacturers cannot be compelled to disclose it.” The court concluded that the state’s interest—which amounted to mere “consumer curiosity”—was “not a strong enough state interest to sustain the compulsion of even an accurate, factual statement.”

**D. The 2016 National Bioengineered Food Disclosure Standard May Shift the Focus of Labeling Towards Production Processes**

However, 2016 marked a narrow shift away from the safety and composition-focused requirements for food labeling. In July 2016, Congress passed the National Bioengineered Food Disclosure Standard, which was

---

71. Id. at 97 (citing Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 55 (1997)).
72. Id. at 96–97.
73. Id. (citation omitted).
74. Id. at 97–98.
75. 92 F.3d 67 (2d Cir. 1996).
76. Id. at 74 (“Because Vermont has demonstrated no cognizable harms . . . its statute is likely to be held unconstitutional.”).
77. Id.
78. Id. (“Instead those consumers interested in such information should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it.”).
79. Id.
signed into law by President Barack Obama. The National Bioengineered Food Disclosure Standard requires the USDA to implement a national GMO labeling standard. This requires the USDA to decide how much GMO content will require disclosure. The legislation requires a text label, a symbol, or an electronic code readable by smartphone to indicate if a food product contains any GMOs. However, products derived from animals that consume food containing or produced from a bioengineered food do not require a label under the Act.

Proponents of the National Bioengineered Food Disclosure Standard argue that since the long-term safety effects of GMOs are unknown, consumers should be able to assess the risks for themselves. The labels could therefore indicate to consumers that the food product might possibly contain a new allergen. Labeling would arguably increase transparency in the food industry. However, arguments in favor of labeling fail to consider the economic impact that labeling poses on both the industry and the consumer. Furthermore, even if manufacturers use modified cell-lines derived from animals, the animal sources fall cleanly within the express exclusion under the Act.

All sides of the GMO debate voice consumer confusion as their primary concerns against the new labeling Act. Those who tend to favor GMOs in the marketplace trumpet consumer confusion caused by the new labeling scheme and the ill-defined, but ever popular, natural food label. By referring
to GMOs as “bioengineered,” the Act also deceptively labels foods since “most consumers don’t know what that means.”

Furthermore, while the Act requires labeling for bioengineered foods, absent from the Act is any definition of what it means to be neither engineered nor natural. In recent years, growing popularity of health foods brought with it a correlated rise in food marketing claims for natural foods. Unsubstantiated natural claims on food labels have resulted in extensive litigation. Opponents fear Congress’s failure to define what it means to be natural could increase consumer confusion and add to the burden on the courts.

GMO opponents argue the USDA fails to adequately address their safety concerns through its new labels. In 2018, the USDA issued a series of “smiley face” labels to accomplish its goals under the Act. The originally

89. Wenonah Hauter, USDA’s GMO Labeling Rule Keeps Consumers in the Dark for the Sake of Big Ag Profits (Dec. 20, 2018), https://www.foodandwaterwatch.org/USDA%20GMO%20Labeling%20Rule%20Deceptive; Groups Offer Reaction to Bioengineered Labeling Standard, FARMPROGRESS (Dec. 20, 2018), https://www.farmprogress.com/farm-policy/groups-offer-reaction-bioengineered-labeling-standard; see also Claire Marris, Public Views on GMOs: Deconstructing the Myths, 2 EMBO REPS. 545, 547 (2001) (recognizing dissonance between how institutions perceive the public’s perceptions of GMOs and the public’s actual perception of GMOs).

90. 7 U.S.C. § 1639b.


proposed labels have been criticized because the labels are not neutral regarding the safety of genetically engineered foods as mandated by the Act.96 Critics argue the “cartoonish characters . . . will undermine consumer trust and lead to confusion, rather than assure neutrality.”97 On August 7, 2018, in an effort to quell public uproar, the USDA filed six new bioengineered food symbols with the U.S. Patent and Trademark Office.98 Under the 2016 National Bioengineered Food Disclosure Standard, the USDA has until 2020 to implement labels with the new bioengineered food symbols.

II. INTEREST GROUPS PRESSURED THE FDA AND USDA TO REEVALUATE THE CURRENT REGULATORY FRAMEWORK

As cell-based meat moves closer to the market, interest groups are increasing pressure on existing regulatory agencies. First, Part II.A discusses the U.S. Cattlemen’s Association petition to exclude cell-based meat from labeling definitions. Second, Part II.B discusses the responses to the petition urging the USDA to disregard the U.S. Cattlemen’s Association petition and label cell-based meat as “meat.” Third, Part II.C discusses pressures on the FDA and USDA to evaluate and coordinate their existing frameworks to regulate cell-based meat. Finally, Part II.D discusses FDA and USDA’s announcement of a joint framework to regulate cell-based meat.

A. The U.S. Cattlemen’s Association Petition—The Lightning Rod that Sparked the Cell-Based Meat Labeling Debate

In the absence of regulations requiring “meat” to be directly sourced from live animals, private interest groups have urged the USDA to narrow its definitions. On February 9, 2018, the USCA filed a petition before the USDA to limit the labeling definition of “beef” and “meat.”99 In its Petition, the

96. Sharon Anglin Treat & Steve Suppan, IATP Comments on “National Bioengineered Food Disclosure Standard,” INST. FOR AGRIC. & TRADE POL’Y (July 10, 2018), https://www.iatp.org/documents/iatp-comments-bioengineered-food-disclosure. The original “smiley face” labels are criticized for being ridiculous and could be an example of sabotaging a law to support proponents of overregulation arguments. Id.
97. Id.
USCA sought to limit beef to “product from cattle that have been born, raised, and harvested in the traditional manner.” The USCA also requested that the broader definition of “meat” be limited to “the tissue or flesh of animals that have been harvested in the traditional manner.” Specifically, the Petition excludes “synthetic product . . . grown in labs from animal cells.” The USCA submitted its petition and urged the Secretary of Agriculture to modify labeling requirements under applicable FSIS regulations.

To support its argument to narrow the definition of “meat” and “beef,” the USCA first explained both the dictionary and statutory definitions of “meat” and “beef.” The USCA cited animal-related definitions to support its petition. Although no animal-based terms were found in the FSIS regulations of beef products, the USCA analogized its narrowed definition to the use of “slaughter” in FSIS policy books. The USCA argued that cell-based meat and beef products are not consistent with accepted definitions of other meat-based products.

The crux of USCA’s argument hinged on the possibility that the current definitions of “beef” and “meat” could potentially create consumer confusion. The USCA cited no evidence of actual confusion but instead relied on the prevalence of new, animal-free alternatives in the market. The USCA cited plant-based burgers from Impossible Foods and Beyond Meat as marketplace competitors that released products to compete with traditional animal-based meat products. With respect to lab-grown meat, the USCA noted “[l]ab[-]grown products are likely to become more prevalent in the market place and thus take market share from natural meat products harvested in the traditional manner.”

100. Id. at 2.
101. Id.
102. Id.
103. 9 C.F.R. §§ 412.1(a)–412.2(b) (2020) (requiring that modifications to the labeling requirements be submitted to the FSIS for approval and that FSIS considers labeling claims for meat on a case-by-case basis).
105. Id. at 6 (“The term ‘aged beef,’ for example, is defined in part as beef ‘maintained in a fresh unfrozen state for a minimum of 14 days from the day of slaughter.’”) (quoting OFF. OF POL’Y, PROGRAM & EMP. DEV., USDA, FOOD STANDARDS AND LABELING POLICY BOOK 9 (2005))).
106. Id. (analogizing to definitions of other meat products such as “beef and gravy”).
107. Id. at 9 (“[A]bsence of a definition of ‘beef’ or ‘meat’ and specific rules and parameters as to what constitutes them is resulting in mislabeling and may lead to consumer confusion.”).
108. Id.
109. Id. at 9–11.
110. Id. at 12.
B. Responses to the USCA Petition Urge the USDA to Label Cell-Based Meat as "Meat"

After extending the comment period,111 FSIS received over 6,150 comments to the USCA Petition.112 Food Safety News reported that the petition "generated significant interest from stakeholders and FSIS got a request on April 10, 2019 to extend the comment period."113 Many interest groups submitted comments to FSIS arguing the Petition was overly broad in scope and jurisdiction.114 This Part discusses three comments submitted to FSIS by (1) Memphis Meats; (2) the North American Meat Institute; and (3) Plant Based Alternative Organizations.

First, Memphis Meats submitted a comment asking FSIS to deny USCA’s petition because it “is not supported by applicable law or longstanding policy.”115 Memphis Meats first submitted its own comprehensive analysis of statutory and regulatory definitions for “meat,” “beef,” and “poultry.”116

Second, Memphis Meats argued that cell-based meat products can fall within the regulatory definitions for “meat” and “poultry.”117 Cell-based meat satisfies these definitions because it is (1) “derived from livestock or a domesticated bird;” (2) “it is part of that animal;” and (3) “it is non-living upon consumption.”118 Memphis Meats argued that the only difference between cell-based meat and animal-derived meat is the process by which

---

113. Lab Meat Comment Period, supra note 111.
114. See, e.g., infra notes 115–132.
116. Id. at 2–4.
117. See id. at 4 (citing 9 C.F.R. §§ 301.2, 381.1) (explaining that the statutory and regulatory definitions for each of these products can be distilled into three distinct requirements that are met by cell-based meat products: “Meat is: (1) derived from certain species of livestock; (2) from a certain part of that animal; and (3) non-living. Similarly, ‘beef’” is defined as the flesh of cattle, and like other meat is from a certain part of cattle and non-living upon consumption. Likewise, a poultry product is: (1) derived from a domesticated bird; (2) is wholly or in part from that bird; and (3) is non-living upon consumption.”).
118. Id. at 5.
the product is grown and harvested. 119  Third, Memphis Meats claimed that USCA’s Petition, if granted, would stifle innovation and “encourage a technological standstill” only benefiting USCA. 120  Fourth, Memphis Meats argued USCA’s Petition disregards established agency policies of “interpret[ing] their existing statutory frameworks . . . [t]o accommodate and appropriately regulate [new] technologies[.]” 121  Finally, Memphis meats urged both the USDA and the FDA to coordinate and create a joint regulatory framework to regulate cell-based meat products “consistent with interagency policy and precedent.” 122

Additionally, the North American Meat Institute (NAMI) called the Petition “ill-considered” and claimed that if the Petition were granted, it likely would cede jurisdiction over to the FDA. 123  The regulatory scheme administered by the FDA, NAMI claims, “is . . . not as rigorous as that imposed by FSIS,” especially “regarding labeling.” 124  NAMI claimed that any intervention by FSIS would therefore “yield chaos in the marketplace.” 125  NAMI also argued that the USCA Petition’s reliance on the Standards and Labeling Policy Book is inappropriate. 126  The Standards and Labeling Policy Book does not have the force and effect of law, 127  As such, incorporating a definition from that Policy Book would “incorporate a new element into a definition . . . using a tool not subject to the Administrative Procedure Act.” 128

119. Id. (“This difference does not mean that the finished product is not ‘meat,’ ‘beef,’ or ‘poultry,’ as demonstrated not only by the relevant statutory and regulatory definitions, but also by the evolution in meat and poultry production and longstanding USDA policy.”).

120. Id. at 6–7 (“Requiring that livestock must be raised and killed in ‘the traditional manner’ in order for products to be labeled . . . only serves to advance Petitioner’s economic interests at the expense of expanded consumer choice in innovative protein products along with advancement in the production of such products.”).

121. Id. at 8–9 (referencing the reinterpretation of regulations in light of genetically modified crops, gene-based modifications of animals, and advanced meat/bone separation technology in meat production).

122. Id. at 1.


125. Id. at 1.


128. Id.
Finally, numerous plant-based meat-alternative producers (hereinafter collectively referred to as GFI) submitted a joint comment to FSIS to reject USCA’s Petition because it only served to protect USCA’s interests. The GFI argued that while USDA is authorized to regulate meat labels to protect customer health and welfare, it is not authorized to do so “to prop up an industry or favor one production method over another.” According to the GFI, “[t]he policy that the [USCA] propose[d] would inhibit innovation across the industry.”

C. Pressure to Evaluate and Coordinate the FDA and USDA Regulatory Frameworks for Cell-Based Meat

In a letter to the Government Accountability Office (GAO), Representative Rosa DeLauro requested a review to determine if cell-based meat required a new regulatory framework. Specifically, Representative DeLauro asked “[w]hat regulatory framework and labeling requirements, if any, exist[ed] in the United States to oversee cell-cultured food products, and to what extent . . . relevant agencies [had] begun preparing for the commercialization of cell-cultured foods.” The letter noted the authority of three agencies that could be invoked in this issue: the FDA, the USDA, and the Federal Trade Commission (FTC). While the FTC is “responsible for enforcing prohibitions against false advertising for, among other things, food


131. Id. at 4–5 (footnotes omitted) (“In 2014, faced with the intersection of the Lanham Act and the [FDCA], the Supreme Court held that ‘the Lanham Act protects commercial interests against unfair competition, while the [FDCA] protects public health and safety.’ The same is true of the FMIA. USDA has no authority to mandate to restrict labels simply to insulate particular producers from competition.” (quoting POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2231 (2014))).

132. The Good Food Institute et al., supra note 130, at 9.


134. Id. at 2.

135. Id. at 1–2.
products,”136 most of the debate centered around the intersection between the FDA and the USDA.

The FDA and USDA have not always seen eye-to-eye on regulating cell-based meat. In July 2018, the FDA held a public meeting on the subject, but did not include speakers from the USDA.137 At the meeting, FDA Commissioner Scott Gottlieb said the FDA’s “past experience with novel food technologies and our extensive background in cell-culture technologies in the medical products space [would] help to inform [its] approach to evaluating the safety of these cell-based food products.”138 Although the USDA previously expected to be involved in regulatory activities, the Commissioner never mentioned the USDA. Although the USDA previously expected to be involved in regulatory activities, the Commissioner never mentioned the USDA. Earlier in April 2018, USDA Secretary Sonny Perdue told House appropriators that although there are “some gray lines between FDA and USDA on many things,” meat has been USDA’s responsibility for many years.139 “We would expect any product that expects to be labeled as meat would come under that same inspection criteria.”140

In August 2018, Memphis Meats and NAMI wrote a joint letter to President Donald Trump and requested that his Administration clarify the regulatory framework for cell-based meat.141 In the letter, Memphis Meats and NAMI argued that the FDA should “have oversight over pre-market safety evaluations for cell-based meat and poultry products.”142 Meanwhile, the USDA “should regulate cell-based meat and poultry products . . . to ensure products are safe, wholesome, and properly labeled.”143 This combined framework “plays into the strengths and experience of FDA and

136. Id. at 2.
138. FDA Meeting Transcript, supra note 137, at 17-18.
139. Id.
140. Id.
142. Id. at 2.
143. Id.
USDA: FDA has extensive expertise regarding products produced using cell culture technology and USDA has a longstanding role in inspecting meat and poultry products.”

This proposed combined regulatory framework was used before with food additives and processes. Mark Dopp, NAMI’s senior vice president for regulatory affairs said that “[d]irect and indirect food additives [are] all approved [] first by FDA for food safety purposes,” and then “FSIS makes sure that they’re used in the proper form or fashion in USDA federally-inspected establishments.”

D. FDA and USDA Announce a Joint Framework to Regulate Cell-Based Meat

In September 2018, Secretary Perdue and Commissioner Gottlieb announced a joint public meeting to discuss the use of cell culture technology to develop products derived from livestock and poultry. “The joint public meeting, hosted by the USDA’s [FSIS] and the FDA, will focus on the potential hazards, oversight considerations, and labeling of cell cultured food products derived from livestock and poultry.” According to the Federal Register notice, the “FDA and FSIS are ‘actively working’ to limit any duplicative and inefficient regulation by the two agencies.” “The labeling and naming issues that proved controversial are also” on the discussion agenda. At the meeting, both Secretary Perdue and Commissioner Gottlieb expressed that innovation was one of the key driving forces that motivated the meeting. Both agency heads also

144. Id.
146. Id.
148. Id.
150. Id.
151. See USDA Meeting Transcript, supra note 28, at 2 (statement of Sonny Perdue) (“It’s very important that we have a framework that encourages innovation and encourages new technology while we provide the responsibility of a public, safe, wholesome, and nutritious food supply[]”); id. at 4 (statement of Scott Gottlieb, FDA Commissioner) (“One of my
expressed an intent to create a joint collaboration between the two agencies.\footnote{152}{See id. (statement of Sonny Perdue) ("Simply put, we're here to talk about how we decide who does what in this arena, how do we come together as one federal government to make the best decisions for the public at large, and how do we make a regulatory framework and protocols that are clear and concise and easily be complied with"); id. at 4 (statement of Scott Gottlieb) ("We fully anticipate that both FDA and USDA will have active roles in the regulatory oversight of cell culture products. The feedback we hear from you today will help us to advance this interagency cooperation and these discussions, as they go forward.").}

On March 7, 2019, as a result of the stakeholder meeting,\footnote{153}{See supra notes 147–152 and accompanying text.} the FDA and FSIS announced a formal agreement to jointly oversee the production of human food products derived from livestock and poultry cells.\footnote{154}{Press Release, USDA, USDA & FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Prods. from Cell Lines of Livestock & Poultry (March 7, 2019), https://www.usda.gov/media/press-releases/2019/03/07/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food. See generally, e.g., Formal Agreement Between the FDA & USDA Off. of Food Safety 1 (Mar. 7, 2019) [hereinafter FDA-USDA Formal Agreement] (outlining the purpose behind the formal agreement between the USDA and FDA), https://www.fsis.usda.gov/wps/wcm/connect/0d2d644a-9a65-43c6-944f-ea598aadced1/Formal-Agreement-FSIS-FDA.pdf?MOD=AJPERES.} Under the agreement, the agencies decided that the FDA will oversee most of the premarket production: cell collection, cell banks, and cell growth and differentiation.\footnote{155}{See id.} “A transition from FDA to FSIS oversight will occur during the cell harvest stage,” and FSIS will oversee the production and labeling of the final food products.\footnote{156}{See id.}

III. **HOW SHOULD THE FDA AND USDA REGULATE AND LABEL CELL-BASED MEAT UNDER THE JOINT FRAMEWORK?**

Since the March 2019 announcement, multiple groups criticized the proposed joint regulatory framework between the FDA and USDA. In comments on the use of cell culture to produce cell-based meat, Memphis Meats’ Vice President of production and regulation, Dr. Eric Schulze, commented, “[a]s currently proposed, it is unclear when and how oversight would be transferred from FDA to USDA, particularly because the proposed framework calls for transfer of oversight ‘during the cell harvest stage,’ and

priorities as Commissioner, is enabling innovation and consumer choice while supporting public health and safety and for the FDA, these products stands at an interesting intersection of medical technology and food technology.”).}
this stage could involve multiple steps.”157 Memphis Meats urged the agencies to establish a more bright-line rule to dictate when the oversight transfer would occur.158 Furthermore, Memphis Meats expressed concerns that the dual-agency oversight would result in unnecessary redundancy through problematic and overlapping inspections.159

In 2005, the FDA and USDA jointly proposed a rule to modernize the standards of identity and composition for food products.160 The agencies aimed to: (1) “better promote honesty and fair dealing in the interest of consumers and protect the public,” (2) “allow for technological advances in food production,” (3) “be consistent with international food standards to the extent feasible,” and (4) “be clear, simple, and easy to use for both manufacturers and the agencies that enforce compliance with the standards.”161 The proposed rules stated that food standards should permit “maximum flexibility in the food technology used to prepare the standardized food, so long as that technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality, or safety of the food.”162

After fifteen years with no further agency action on the proposed rule, the FDA hosted a public meeting on September 27, 2019 to revisit the issue.163 At the meeting, the FDA promised to revisit the 2005 general

---

158. Id.
159. Id. at 12–13 (“This would mean that a cell-based meat or poultry product that will be used as an ingredient in a multi-component food, could be subject to at least three FDA or USDA inspections.”).
161. Id. The agencies included the following motivating statement in the proposed rule: Establishing regulations that do not stifle innovations in food technology and allow for technological alternatives and advancements in food processing would improve manufacturing efficiency and lessen costs which may be passed on to the consumer. Improved technologies may additionally benefit product quality and diversity. Increased diversity in, and potentially lower costs of, food products in the marketplace that continue to meet consumer expectations would promote honesty and fair dealing in the interest of consumers and protect the public.
162. Id. at 29,222.
principles and propose a “horizontal” change, allowing greater flexibility across the broad category of standardized foods. The agency’s commitment to retrofitting the current framework is a light at the end of the regulatory tunnel—it signals that new technologies will likely exist within the bounds of agency standards.

In light of the delay in advancing the regulatory framework and the lack of clarity provided by the agencies, this Article attempts to evaluate two potential areas that the agencies may evaluate novel cell-based meat under existing regulatory regimes. Part III.A discusses the FDA’s premarket regulation of the safety of protein and cell-based food additives. Appendix A compliments Part III.A and proposes an outline for cell-based meat producers to use in their premarket consultation process evaluations with the FDA. Part III.B then discusses the USDA’s regulation of meat recovery products already on the market and proposes that cell-based meat can be regulated using that existing framework.

A. Premarket Regulation by FDA and a Proposed Premarket Consultation Process Outline for Cell-Based Meat

Under the FDA and USDA joint framework to regulate cell-based meat, the FDA agreed to “[c]onduct premarket consultation processes to evaluate production materials/processes and manufacturing controls, to include oversight of tissue collection, cell lines and banks, and all components and inputs.” While the FDA has yet to release guidance or define its premarket consultation process evaluation parameters, regulators can glean insight from the established food additive submission process.

164. Id.


166. See infra Appendix A.


The FDA regulates food safety pursuant to its authority under section 402(a)(1) of the FDCA. Under the FDCA, substances that are food additives may be used in food only in accordance with an authorized regulation. Currently, substances expected to be components of food whose composition has been altered so that the substance is not Generally Recognized as Safe (GRAS) is subject to regulation as “food additives” under section 409 of the FDCA.

The FDA defines GRAS substances as substances that are added to food that are generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of their intended use. A food substance may be established as GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. Manufacturers can either make a self-determination of GRAS, file a notification with the FDA asking that they not object to the self-determination, or file a food additive petition supported by extensive toxicology testing. GRAS notices must contain specific sections as outlined in the applicable regulations.

Because there are no existing premarket consultation process evaluations or GRAS notices for cell-based meat products, future producers and regulators need to synthesize a new outline for their premarket consultation process submissions to the FDA. There are many GRAS submissions for protein-based food additives and cell-based food additives, and any future premarket consultation submissions for cell-based meat will likely contain characteristics from both food additive GRAS notice classes. Here, protein-
based GRAS notices are initially analyzed, followed by cell-based GRAS notices.177

First, Impossible Foods developed a patented method to produce its soy leghemoglobin using genes from soy root nodules.178 Impossible Foods used genetically modified yeast, *Pichia pastoris*, to express the soy hemoglobin gene.179 Soy leghemoglobin is the closest food product to cell-based meat identified in the FDA’s GRAS notice database because it is a protein component produced through cell culture techniques.180 The GRAS notice for Impossible Foods’ soy leghemoglobin sets out many guidelines that manufacturers of cell-based meat would likely need to meet in their GRAS notice. However, the major drawback for comparing soy leghemoglobin to cell-based meat is that soy leghemoglobin is produced through yeast cell expression, while cell-based meat will be produced through culturing animal muscle or stem cells.

Second, Proteus Industries, Inc. (Proteus) developed a method to extract protein—here “beef protein”—from trimmings using a solubilizing citric acid wash.181 Proteus also submitted other GRAS notices for other species proteins.182 Here, the “beef protein” submission is most relevant to the issue

176. See infra notes 178–184 and accompanying text.
177. See infra notes 185–189 and accompanying text.
178. Impossible Foods submitted a GRAS notification to the FDA on soy leghemoglobin protein production in 2017. See generally GRAS Notification from Impossible Foods Inc. to FDA 22–25 (Oct. 2, 2017) (on file with the FDA, GRN No. 737) [hereinafter GRN 737], https://www.fda.gov/media/124351/download (providing narrative background on the company’s proposed protein strain for food consumed by humans).
179. Id. at 25.
180. Id. at 22–23 (further explaining soy leghemoglobin morphology).
of regulating “beef” or “meat,” and the use of “beef protein” will also be subject to inspection by USDA’s FSIS. Extracted “beef protein” is added as a protein filler to other beef products. In anticipation of their premarket consultation submissions, manufacturers of cell-based meat should also consult the GRAS notices of the other species-products.

Third, Chr. Hansen Inc. submitted a GRAS notice for use of *Lactobacillus curvatus* as a cell-based food additive to suppress the growth of *Listeria monocytogenes*. The cells are added to the final beef products and remain on the product through storage. While Chr. Hansen Inc.’s GRAS notice was instructive on the requirements for cell-based food additives, the cells used were bacterial and not animal cells.

Finally, Functional Technologies Corp. submitted a GRAS notice for use of *Saccharomyces cerevisiae*, modified baker’s yeast as a food preservative. The modified baker’s yeast contains a gene to reduce acrylamide formation in food products. The modified baker’s yeast is eukaryotic, which is evolutionarily closer to animal-cells than bacterial cells.

In sum, the proposed premarket consultation submission outline is meant to be a starting point for cell-based meat manufacturers and regulators. One major hurdle for cell-based meat producers is the relative proportion of their cultured cells in the final meat product. The GRAS notices analyzed here are for products that are single components in larger multicomponent products. Compared to cell-based meat, these GRAS

183. GRN 313, *supra* note 181, at 3.

184. *Id.* at 6.

185. See GRAS Notification from Chr. Hansen, Inc. to FDA 5 (Jan. 31, 2018) (on file with the FDA, GRN No. 760) [hereinafter GRN 760], https://www.fda.gov/media/125424/download.

186. *Id.*

187. *Id.*


189. *Id.*

190. See *infra* Appendix A.
products make up a much smaller amount in the final product. Cell-based meat, however, is expected to make up the majority or a much larger proportion of the final product. Therefore, the FDA may likely scrutinize cell-based meat to a higher degree.

B. Current USDA Regulatory Schemes Permit Cell-Based Meat to Be Labeled Using the Common or Usual Name.

While the FDA will handle cell culture GRAS approval of cell-based meat production, the USDA will take over the final stages of production and labeling. Because cell-based meat is a novel food source, questions remain over how the USDA will label the final product. However, based on the current USDA framework, regulators should label cell-based meat as according to the product’s common or usual name.

The FMIA and Poultry Products Inspection Act (PPIA) authorize FSIS to promulgate common or usual names for meat and poultry products. FSIS regulations state that “any product for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products, insofar as specific ingredients or procedures are not [otherwise] prescribed or prohibited.” In contrast to the common or usual names, manufacturers are only required to label their product as “imitation” if the product is nutritionally inferior to the standardized product. Because cell-based meat manufacturers aim to mirror the exact composition of standardized meat and poultry products, the final product will not be nutritionally inferior. Thus, cell-based meat products should be labeled according to the common or usual name of the standardized product, and they should not be required to bear an “imitation” label.

The USDA also mandated additional labeling requirements for other meat products that differed from the composition of standardized meat:

192. 21 U.S.C. § 457(c).
194. See USDA, Food Safety Inspection Serv., Policy Memorandum on Labeling for Substitute Products (Mar. 23, 1984), https://www.fsis.usda.gov/wps/wcm/connect/92485d36-be7c-451b-9153-7a921b13d72/Policy_Memos_101818.pdf?MOD=AJPERES ("[N]utritional inferiority is defined, consistent with the requirement of 21 C.F.R. § 101.3(c)(4), as any reduction in the content of an essential nutrient that is present at two percent or more of the U.S. [Recommended Dietary Allowance (RDA)] per serving of protein or any of the vitamins or minerals for which U.S. RDAs are established.").
195. Id.
Mechanically Separated Meat (MSM). MSM is a food product produced from forcing bones with attached meat trimmings through a high-pressure sieve. The final product is a “paste-like” meat product composed mostly of protein. However, MSM also contains some bone fragments. Because of the changes in composition compared to traditionally butchered meat, most notably the increase in calcium, the USDA did not permit manufacturers to label the product as the common or usual name for “meat.” In 1982, the USDA permitted the product to be used in human food, so long as the label listed MSM as an ingredient. This labeling requirement for MSM supports the conclusion that the USDA requires additional labeling for meat products only where the meat is different in composition compared to traditional meat.

In contrast to MSM, the Memphis Meats response to the USCA Petition notes that the USDA allows meat products derived from animal sources, such as advanced meat/bone recovery (AMR) technology, to be labeled as their common or usual name. AMR mechanically removes remaining meat trimmings from bone through scraping or shaving, but AMR machinery cannot “grind, crush or pulverize bones.” The USDA sets limits on the amount of calcium in the final product to be “no more than 130 milligrams


197. Id.

198. Id.

199. Cf. id. (noting that “bones with attached edible meat” are put through a sieve to remove the edible meat).


201. USDA FOOD SAFETY & INSPECTION SERV., supra note 196. Previously, Mechanically Separated Meat (MSM) was required to be prominently displayed on the front of the label, but the new regulation required it to be listed only in the ingredients. See Mark Seidenfeld, A Big Picture Approach to Presidential Influence on Agency Policy-Making, 80 IOWA L. REV. 1, 16 (1994).

202. See USDA FOOD SAFETY & INSPECTION SERV., supra note 196. The USDA does not permit the sale or consumption of mechanically separated beef. Id. (“Due to FSIS regulations enacted in 2004 to protect consumers against Bovine Spongiform Encephalopathy, mechanically separated beef is considered inedible and is prohibited for use as human food”); e.g., 9 C.F.R. § 381.173 (2019) (Mechanically Separated Poultry).

203. See text accompanying note 121; see also 9 C.F.R. § 318.24 (2019) (enumerating regulations for advanced meat/bone separation process).

204. See USDA FOOD SAFETY & INSPECTION SERV., supra note 196.
of calcium per 100 grams product.” Product exceeding this limit must be labeled as MSM, and MSM must be listed as an ingredient where it is added to a final product. Thus, the USDA allows AMR products to be labeled as “meat” or “poultry” because the products are “comparable in appearance, texture and composition” to butchered meat or poultry products.

So long as cell-based meat conforms to the meat composition requirements set out by the USDA, it should be labeled according to the common or usual name of the product. Labeling cell-based meat and poultry products by the common or usual name conforms to current regulations in line with “imitation,” AMR, and MSM labeling requirements. If the cell-based meat product conforms to the same standards of identity as traditional butchered meat, it should be labeled with its common or usual name. Unlike the case with plant-based meat products—where the final product contains no animal cells and requires additional labeling to avoid consumer confusion—cell-based meat products do not present potential consumer confusion because the final product will contain the same components as traditional butchered meat. If the USDA required additional labeling for a product with no material differences compared to butchered meat and poultry, the USDA would likely cause consumer confusion.

Furthermore, labeling cell-based meat and poultry products by their common or usual names would align with the USDA’s past labeling trends. In years past, the USDA operated its food labeling regulatory scheme primarily to address food safety concerns rather than the method in which the food was developed. Although the 2016 National Bioengineered Food Disclosure Act requires additional labeling for GMO products, that law does not apply to products derived from animals. Furthermore, the new GMO labeling Act was motivated by arguments that the long-term effects of GMOs are unknown and consumers should be able

---

205. Id.
206. Id.
207. Id.; Memphis Meats, supra note 115, at 9–10.
208. See supra notes 192–207 and accompanying text.
209. See supra notes 17–22 and accompanying text (explaining how inconsistent product labels lead to consumer confusion).
210. See supra notes 70–79 and accompanying text (describing the development of food labeling process in the United States).
211. See supra notes 700–79 and accompanying text (explaining that food manufacturers are not required to disclose information regarding the development process without proof of a potential health risk).
212. See supra notes 84 and accompanying text (describing the labeling requirements for bioengineered food).
to assess the risks for themselves. In contrast to GMOs, cell-based meat products are not expected to have any different health risks because the cells are derived from animal sources that have been consumed for hundreds of years. Moreover, in line with criticisms of added GMO labeling, any additional labeling requirements on cell-based meat would create more consumer confusion because most consumers will not understand what cell-based meat means.

CONCLUSION

Simply put, cell-based meat should be regulated and labeled as “meat.” The FDA and USDA have made great strides to begin creating a joint regulatory framework to oversee the production and sale of cell-based meat. In the coming years, manufacturers should look to previous GRAS notices for both protein-based and cell-based food additives. This Article offers a proposed premarket consultation submission outline for manufacturers and regulators to add to for their future FDA submissions. The proposed outline includes only components from GRAS notifications, and will likely need to be supplemented with components from food additive submissions. Furthermore, current regulations around labeling requirements for AMR permit the USDA to label cell-based meat and poultry under the current common or usual names. Labeling cell-based meat and poultry under their common or usual name would align with the USDA’s trend of safety-related labeling. Regulating and labeling cell-based meat-like “meat” both allows manufacturers to compete with other food producers and promotes innovation.

213. See supra note 85–86 and accompanying text.
214. See supra note 899 and accompanying text.
215. See supra Part IV.B.
216. See infra Appendix A.
217. See infra Appendix A.
218. See supra notes 192–194 (comparing the common or usual name labeling requirements with “imitation” labeling requirements), 197–202 and accompanying text (explaining MSM standards and labeling requirements), 203–207 and accompanying text (discussing Advanced Meat Recovery standards and labeling requirements).
219. See supra notes 70–79 and accompanying text.
A. Proposed Premarket Consultation Submission Outline for Cell-Based Meat

2. Part 2: Identity, Method of Manufacture, Specification, and Physical or Technical Effect.\textsuperscript{220}
   2.1. Biological name\textsuperscript{221}
   2.2. Common or usual name\textsuperscript{222}
   2.3. Cell source\textsuperscript{223}
   2.4. Phenotypic characteristics\textsuperscript{224} of cells
   2.5. Antibiotic resistance\textsuperscript{225}
   2.6. Genetically modified status\textsuperscript{226}
   2.7. Selection mechanism\textsuperscript{227}
   2.8. Applicable conditions of use\textsuperscript{228} including macro-analysis for composition of protein, oil, water, and miscellaneous ingredients including salt, flavors, vitamins, essential amino acids, etc.\textsuperscript{229}
   2.8.1. Levels of use of the cultured cell product in the final food product\textsuperscript{230}
   2.8.2. Purposes of characterizing components of the cultured cells–flavor, nutrition, texture, etc.\textsuperscript{231}
2.9. Composition\textsuperscript{232} of the cultured cells including species origin
2.10. Specifications for food grade material\textsuperscript{233}
   2.10.1. Identity and Specifications\textsuperscript{234} of the cell-based meat

\textsuperscript{220} GRN 737, supra note 178, at 6.
\textsuperscript{221} Id.; GRN 313, supra note 181, at 4–5; GRN 760, supra note 185, at 7.
\textsuperscript{222} GRN 737, supra note 178, at 6; GRN 313, supra note 181, at 4–5; GRN 760, supra note 185, at 7; GRN 422, supra note 188, at 8.
\textsuperscript{223} GRN 760, supra note 185, at 7; GRN 422, supra note 188, at 11.
\textsuperscript{224} GRN 760, supra note 185, at 7–8; GRN 422, supra note 188, at 11.
\textsuperscript{225} GRN 760, supra note 185, at 8.
\textsuperscript{226} Id.; GRN 422, supra note 188, at 12–13.
\textsuperscript{227} Id. at 14–15 (discussing the yeast URA3-ASP3 selection strategy).
\textsuperscript{228} GRN 737, supra note 178, at 6; GRN 313, supra note 181, at 5.
\textsuperscript{229} GRN 737, supra note 178, at 6.
\textsuperscript{230} Id.
\textsuperscript{231} Id. at 6–7.
\textsuperscript{232} Id. at 7.
\textsuperscript{233} Id. at 8.
\textsuperscript{234} GRN 313, supra note 181, at 8–9 (using sodium dodecyl sulfate-polyacrylamide gel electrophoresis (SDS-PAGE) to compare protein product with meat currently available for
2.10.2. Intended use and amount required

2.10.3. Moisture, protein, lipid, and phospholipid content

2.10.4. Micronutrient comparison

2.10.5. Amino acid profile of the cell-based meat compared to comparable meat products

2.11. Method of manufacture establishing each step of the growth protocol

2.11.1. Raw materials including cell source, growth medium, cell culture facility requirements

2.11.2. Cell culture protocol

2.11.3. Cell harvest and recovery process

2.11.4. Cell/protein recovery specifications

2.12. Strain construction of the cell line

2.12.1. Cell source

2.12.2. Genotype

2.12.3. Maintenance of the cell line

2.12.4. Stability of the cell line

2.12.5. Absence of antibiotic resistance genes

2.12.6. Absence of other selection genes

2.13. Potential toxicants

human consumption. SDS-PAGE is a common lab technique used to separate denatured, or unfolded, proteins by mass along a polymer matrix using electrical current. Id. SDS-PAGE gels are then imaged, and the visible stained “bands” in each sample are compared using densitometry or mass spectrometry. Id.

235. GRN 760, supra note 185, at 12.

236. GRN 313, supra note 181, at 16.

237. For a breakdown of the macro and micro nutrients analyzed, see GRN 737, supra note 178, at 9 (batch analyses from at least five independent production runs, comparing each of the five runs to the reference).

238. GRN 313, supra note 181, at 15.

239. GRN 737, supra note 178, at 10; GRN 313, supra note 181, at 11–13; GRN 760, supra note 185, at 9.

240. GRN 760, supra note 185, at 10.

241. GRN 313, supra note 181, at 14 (adjusting the final salt percentage of the protein product using the “Standard curve for Brix% versus protein concentration” (citing A.G. Gornall, et al., 177 J. BIOL. CHEM. 751 (1949))).

242. GRN 737, supra note 178, at 11.

243. Id. at 15.

244. Id. at 16; GRN 760, supra note 185, at 11 (“shelf life”).

245. GRN 737, supra note 178, at 16.

246. Id.

247. Id.
   3.1. Estimated dietary intake ("EDI").
   3.2. Estimation of the 90th percentile intake for cultured cells.
   6.1. History of safe use.
      6.1.1. Cells used—animal source of cells
      6.1.2. Protein product—types of meat products existing composed of those cells
      6.1.3. Cell line grown in lab
      6.1.4. Method of manufacturing
      6.1.5. Lack of brain, trigeminal ganglia, spinal cord tissue, or dorsal root ganglia in the final product.
   6.2. Summary of adverse findings in the literature.
   6.3. Toxicology studies.
      6.3.1. Subacute toxicity—14d dietary toxicity/palatability study in rats
      6.3.2. Repeated dose toxicity
         6.3.2.1. 28d dietary toxicity study in rats
         6.3.2.2. Pathology peer review on 28d toxicity study in rats
         6.3.2.3. No Observed Adverse Effect Level.

248. Id. at 17; GRN 760, supra note 185, at 14–15.
249. GRN 737, supra note 178, at 17.
250. Id. at 18–19.
251. Id. at 20; GRN 313, supra note 181, at 17; GRN 760, supra note 185, at 15.
252. GRN 737, supra note 178, at 22.
253. Id. at 22; GRN 313, supra note 181, at 17–21.
254. GRN 760, supra note 185, at 16–17; GRN 422, supra note 188, at 19.
255. GRN 737, supra note 178, at 22 (specifying “soy” and “soy leghemoglobin”); GRN 313, supra note 181, at 20.
256. GRN 737, supra note 178, at 24; GRN 422, supra note 188, at 21–23.
257. GRN 737, supra note 178, at 25.
258. GRN 313, supra note 181, supp. at 2 (June 29, 2010) (responding to FDA’s first Question regarding GRN 313 and GRN 314).
259. GRN 737, supra note 178, at 25.
260. Id.
261. Id.
262. Id. at 26–30.
263. Id. at 31.
264. Id. at 26, 31.
6.3.3. Mutagenicity/Genotoxicity studies\textsuperscript{265}
6.4. Assessment of Allergenicity\textsuperscript{266}
   6.4.1. Assessment of potential cross-reactivity\textsuperscript{267} only if new genes are introduced into the cultured cells
   6.4.2. Pepsin digestion\textsuperscript{268} to determine the stability of proteins in cultured cells
6.5. Safety testing\textsuperscript{269}
7. Part 7: List of Supporting Data and Information in GRAS Notice

\textsuperscript{265} Id. at 31 (“Reverse Mutation Assay” and “\textit{In Vitro} Mammalian Chromosome Aberration Test in Human Lymphocytes”).
\textsuperscript{266} Id. at 34.
\textsuperscript{267} Id. at 34–40 (comparing cross-reactivity of soy and yeast genomes).
\textsuperscript{268} Id. at 40.
\textsuperscript{269} Id. at 41.