# FROM PETRI DISH TO MAIN DISH: THE LEGAL PATHWAY FOR CELL-BASED MEAT

*Brian P. Sylvester,*[‖] *Nathan A. Beaver,*[‡] *Kara Schoonover,*[*] *Jonathan I. Tietz*[†]

ABSTRACT

*Meat grown outside an animal is no longer simply science fiction, and the market is poised for introduction of a variety of so-called cell-based meat products. Commercializing these products will require a clear regulatory path forward. In this Article, we explore that legal pathway. We introduce the concepts of cellular agriculture and cell-based meat, including the science, the state and history of the industry, and the general regulatory background, in which the USDA and FDA are the major players. Further, we explore in particular regulatory aspects of food safety and labeling in the context of cell-based meat. Overall, we contend that there is a viable pathway forward for cultivated-meat companies under the current regulatory scheme. But a nontrivial degree of uncertainty remains, and regulators would do well to be proactive in issuing guidance in this space. Moreover, cell-based meat remains vulnerable to legal challenges.*

[‖] Special Counsel, Covington & Burling LLP. JD, Cornell Law School, 2008. Mr. Sylvester, the lead author, would like to thank his colleagues, past and present, for their unwavering support and training in food law which has given rise to his thought leadership in this burgeoning sector on a range of first impression issues. The authors thank Liz Shelton, Pamela Noyd, and Linda Lange for valuable research assistance.

[‡] Partner, Foley & Lardner LLP. JD, Georgetown University Law Center, 1997.

[*] Associate, Foley & Lardner LLP. JD, Georgetown University Law Center, 2019.

[†] Law Clerk, United States Court of Appeals. JD, University of Michigan Law School, 2019. PhD (Chemistry), University of Illinois at Urbana-Champaign, 2016.

CONTENTS

## INTRODUCTION

In 2013, journalists gathered in London to taste a burger. It was dry, and, as far as burgers go, it was not a particularly impressive morsel.[1] One taster described it as "close to meat."[2] Said another, "the general bite feels like hamburger."[3] These reviews were perhaps underwhelming, given the burger's $330,000 price tag.[4] Still, it was unlike any burger created before: no animal had been slaughtered to make it.[5] The burger, a product of Dr. Mark Post's research efforts, was the first successful public proof of concept of meat grown outside the animal, commonly referred to as lab-grown, or cell-based meat.[6]

Less than a decade later, the market is poised for the introduction of various cell-based meat products by several companies that reportedly more closely resemble meat obtained from slaughter—products including meatballs, beef steak, salmon, burgers, duck, tuna, chicken nuggets, and more. They are still expensive,[7] but the expected price tags are far lower than $330,000 per quarter-pounder (which is about sixty times the price of gold). Indeed, some estimates project a cost of about $10 per hamburger patty by 2021.[8]

---

[1] G. Owen Schaeffer, *Lab-Grown Meat*, SCI. AM. (Sept. 14, 2018), https://www.scientificamerican.com/article/lab-grown-meat/ [https://perma.cc/LPK7-B75C].

[2] *World's First Lab-Grown Burger Is Eaten in London*, BBC NEWS (Aug. 5, 2013), https://www.bbc.com/news/science-environment-23576143 [https://perma.cc/Y8EN-PDGN].

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] Consider Memphis Meats' $18,000-per-pound meatball in 2016. Marta Zaraska, *Lab-grown meat is in your future, and it may be healthier than the real stuff*, WASH. POST (May 2, 2016), https://www.washingtonpost.com/national/health-science/lab-grown-meat-is-in-your-future-and-it-may-be-healthier-than-the-real-stuff/2016/05/02/aa893f34-e630-11e5-a6f3-21ccdbc5f74e_story.html [https://perma.cc/X3K3-XRA3]. Similarly, consider Finland Foods' $4,000-per-pound tuna or Aleph Farms' $50 steak. *See* Mischa Frankl-Duval, *Lab-Grown Meat is Coming, but the Price is Hard to Stomach*, WALL ST. J. (May 2, 2019, 10:00 AM), https://www.wsj.com/articles/lab-grown-meat-is-coming-but-the-price-is-hard-to-stomach-11556805600 [https://perma.cc/RW9Q-7DYW].

[8] Nicole Axworthy, *Price of Lab-Grown Meat to Plummet from $280,000 to $10 per Patty by 2021*, VEGNEWS. (July 14, 2019), https://vegnews.com/2019/7/price-of-lab-grown-meat-to-plummet-from-280000-to-10-per-patty-by-2021 [https://perma.cc/NTH9-M4DP].

Supporters of cell-based meat point to environmental and sustainability,[9] health,[10] and ethical[11] reasons behind the development of their products. For instance, eating four pounds of conventionally produced beef (about a month's worth for the average American) has the same carbon footprint as flying from New York to London.[12] This impact could be dramatically reduced: one study published in 2011 estimated that lab-grown meat would require 7–45 percent lower energy use, 78–96 percent lower greenhouse gas emissions, and 1 percent of the land use of conventionally produced meat.[13]

Science has grown apace, with a spike in recent interest and tens of millions of dollars in private research funding in the last few years.[14] More recent instances of cell-based meat, aided by advances in cell culture and engineering methods, look and taste much more convincingly like the conventional version.[15] Still, some point out that cell-based meat remains woefully publicly underfunded—even so, scientific publications discussing cell-based meat have rapidly increased in number the last half-decade,[16] and innovative startups tout their advances in technology.

Despite rapid advances in the underlying science and technology, however, cell-based meat faces obstacles.[17] One is

---

[9] *See, e.g.*, Tad Friend, *Can a Burger Help Solve Climate Change?*, NEW YORKER (Sept. 23, 2019), https://www.newyorker.com/magazine/2019/09/30/can-a-burger-help-solve-climate-change [https://perma.cc/E7UP-DAFS].

[10] *See* Zaraska, *supra* note 7.

[11] *See* Schaeffer, *supra* note 1.

[12] Friend, *supra* note 9.

[13] Hanna L. Tuomisto & M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, 45 ENVTL. SCI. & TECH. 6117 (2011).

[14] Elie Dolgin, *Sizzling Interest in Lab-Grown Meat Belies Lack of Basic Research*, 566 NATURE 161 (2019).

[15] Knvul Sheikh, *Lab-Grown Meat That Doesn't Look Like Mush*, N.Y. TIMES (Oct. 27, 2019), https://www.nytimes.com/2019/10/27/science/lab-meat-texture.html [https://perma.cc/UYG8-UASW].

[16] *See, e.g.*, *Cultured Meat*, PUBMED, https://www.ncbi.nlm.nih.gov/pubmed/?term=cultured+meat [https://perma.cc/G46M-JN36]. For instance, a search of the PubMed database for relevant keywords ("cultured meat" or "in vitro meat" or "lab-grown meat" or "cultivated meat" or "cell based meat") yields seventy-three results from 2018, in comparison with just twenty-nine in 2013 and twenty-two from 2008.

[17] Katy Askew, Cultures Meat: Challenges and opportunities on the long road to market, FOOD NAVIGATOR (Dec. 17, 2019 1:46 PM),

cost.[18] Although high prices for cell-based meat could situate it as a luxury good, high prices also stand to drive away consumers and slow the industry's growth.[19] Another is branding. There is no agreed consensus on what to *call* it, with various competing and not-quite-satisfying terms—take, for instance, "cultured meat," "in vitro meat," "lab-grown meat," "cell-based meat," "clean meat," "fake meat," "alt-meat," "synthetic meat,"—bouncing around in the absence of a market-wide consensus.[20] And how to market it?[21] Emphasize its similarity to conventional products, or distinguish its differences?

Still another challenge is consumer demand. As opponents point out, many consumers find the very concept of meat grown by cell culture unpalatable on a gut level.[22] Of course, many consumers might find the workings of slaughterhouses stomach-turning too.[23]

Even beyond these market-based concerns, however, an important set of legal obstacles looms: just what *is* the legal pathway from the laboratory bench to the dinner plate? Food is a highly regulated industry, and the pertinent rules in the United States do not squarely address these products. That is not particularly surprising, given the cutting-edge nature of the technology.

---

https://www.foodnavigator.com/Article/2019/12/17/Cultured-meat-and-the-long-road-to-market# [https://perma.cc/6HE2-RSDR].

[18] *Id.*

[19] Mischa Frankl-Duval, *supra* note 7.

[20] Sarah Zhang, *The Farcical Battle Over What to Call Lab-Grown Meat*, THE ATLANTIC (July 13, 2018), https://www.theatlantic.com/science/archive/2018/07/lab-grown-meat/565049/ [https://perma.cc/LVD3-XVX].

[21] *See, e.g.*, Samantha Henig, *Lab Meat, Rebranded*, NEW YORKER (May 18, 2011), https://www.newyorker.com/news/news-desk/lab-meat-rebranded [https://perma.cc/8PF8-7Z7X].

[22] *See* Sheikh, *supra* note 15 (citing consumer "squeamishness"); Friend, *supra* note 9 (reporting one industry executive's objection to the "long list" of ingredients in alternative meats). *But see* Jacy Reese, *Is the World Ready for Lab-Grown Meat?*, GUARDIAN (Mar. 3, 2019, 9:05 AM), https://www.theguardian.com/commentisfree/2019/mar/03/clean-meat-lab-grown-china-india [https://perma.cc/G34R-NFD4] (reporting that 53% of Americans would try lab-grown meat, and that the proportion of willing consumers is even higher abroad).

[23] *See, e.g.*, Michael Specter, *Test-Tube Burgers*, NEW YORKER (May 16, 2011), https://www.newyorker.com/magazine/2011/05/23/test-tube-burgers [https://perma.cc/6EYE-39V7] ("'I wonder how people would feel if, at the beginning of a [Food Network] show, the stars pulled a darling little lamb onto the stage and then beheaded, gutted, and skinned it,' Ingrid Newkirk said. 'I am thinking that the ratings would fall.'").

Developments in food-related technology have traditionally seen challenges in the face of the regulatory and market status quo, with accompanying battles between proponents who herald advances in technology and opponents who caution against consumer confusion and safety considerations[24]—a battle between innovation and tradition, between free competition and economic protectionism.

In this Article, we explore the legal pathway for cell-based meat.[25] In Part I, we introduce the concepts of cellular agriculture and cell-based meat, including briefly reviewing the science, the state and history of the industry, and the general regulatory background, in which the USDA and US Food and Drug Administration ("FDA") are the major players. In Part II, we explore in particular regulatory aspects of food safety in the context of cell-based meat. In Part III, we discuss the regulatory considerations surrounding product labeling of cell-based meat. Overall, we contend that there is a viable pathway forward for cultivated-meat companies under the current regulatory scheme. However, a nontrivial degree of uncertainty remains, and regulators would do well to be proactive in issuing guidance in this space. Moreover, cell-based meat remains vulnerable to legal challenges.

## I. THE STATE OF CELLULAR AGRICULTURE

In this Part, we survey the state of cellular agriculture as it pertains to cell-based meat. In Section I.A, we explore the nature of cellular agriculture, including the general process of making cell-based meat as well as the history of cell-based meat in the United States. In Section II.B, we introduce the current market landscape, including the major producers and other interested organizations. Then, in Section III.C, we introduce the regulatory

---

[24] *See generally* DEBORAH BLUM, THE POISON SQUAD: ONE CHEMIST'S SINGLE-MINDED CRUSADE FOR FOOD SAFETY AT THE TURN OF THE TWENTIETH CENTURY (2018) (recounting these themes in the development of food safety laws in the United States in the early twentieth century).

[25] A reader of the cultivated-meat literature will notice that terminology changes frequently, as this is a rapidly evolving field. In this Article, we use the term "cell-based meat" throughout to refer to meat (including seafood) produced through cellular agriculture, and we treat the term here as equivalent to "in vitro meat," "lab-grown meat," "cultivated meat," "clean meat," and other synonymous terms.

backdrop in the United States, in which the Food & Drug Administration ("FDA") and US Department of Agriculture ("USDA") are the major regulators of food safety and labeling.

## *A. The Nature of Cellular Agriculture*

### *1. The Basics*

"Cellular agriculture" is "the production of agricultural products from cell cultures."[26] The term encompasses animal cell culture food technology: the "controlled growth of animal cells from livestock, poultry, fish, or other animals, their subsequent differentiation into various cell types, and their collection and processing into food."[27] In their ideal forms, the products of this technology—cell-based meat—look, smell, and taste just like conventionally produced meat.[28]

Producing cell-based meat involves first taking a small sample of cells from an animal (i.e., a biopsy).[29] The sample might involve a mixture of desired and undesired cell types, so the desired ones are isolated before themselves being placed among nutrients and allowed to reproduce (i.e., proliferate).[30] This process may involve any number of additional components, including cell nutrients, cell scaffolds (to lend the meat three-dimensional structure and texture as it grows), and the addition of various factors that can differentiate cells.[31]

Culturing cells is complicated because outside a mammalian body, cells are fragile things. Indeed, mammalian cells require a nutrition-rich, water-based medium with controlled sterility, temperature, acidity, ionic balance, oxygen level, and

---

[26] Brian P. Sylvester, *FDA Tackles Cell-Cultured Foods*, FOOD & DRUG L. INST. (July 2018), https://www.fdli.org/2018/07/fda-tackles-cell-cultured-foods/ [https://perma.cc/6JMU-X5WU]; *What Is Cellular Agriculture?*, NEW HARVEST, https://www.new-harvest.org/cell_ag_101 [https://perma.cc/LJ5Y-YAP3].

[27] *October 2018 Joint USDA-FDA Meeting*, *infra* note 166.

[28] Mike Brown, *How Does a Lab-Grown Burger Taste? Similar to McDonald's, Say Scientists*, INVERSE (July 7, 2019, 7:00 AM), https://www.inverse.com/article/57865-how-does-a-lab-grown-burger-taste-similar-to-mcdonald-s-say-scientists [https://perma.cc/3E9P-W6HF].

[29] *See* Trae Norton, Comment, *From the Lab to the Supermarket: In Vitro Meat as a Viable Alternate to Traditional Meat Production*, 11 J. FOOD L. & POL'Y 157, 163 (2015).

[30] *See, e.g.*, Zachary Schneider, Comment, *In Vitro Meat: Space Travel, Cannibalism, and Federal Regulation*, 50 HOUS. L. REV. 991, 1001(2013).

[31] *Id.* at 999 (describing scaffold-based production methods).

other parameters, or they die.[32] Even with perfectly hospitable conditions, most cell types will die anyway due to inherent limitations in most cells that prevent their long-term reproduction.[33] Cells reproduce by dividing—that is, one parent cell becomes two daughter cells.[34] Cells can also develop from one type into another (e.g., from a stem cell to a fat cell or muscle cell) through a process known as cell differentiation.[35] Division and differentiation may be influenced by the addition of chemical compounds, such as growth factors or transcription factors, that cause cells to change their physiological functions.[36] Importantly, division and differentiation require the use of a particular cell type suited to those functions.[37]

Moreover, in the traditional laboratory setting, cell culture entails growing (usually) one type of homogeneous cell.[38] In contrast, meat often consists of multiple cell types (e.g., muscle and fat cells) arranged in a heterogeneous, three-dimensionally structured manner: consider, for example, a well-marbled steak, or a fish filet with layers of muscle and fat and skin.[39] With this complexity come significant engineering challenges.[40] Accordingly, the process of getting from an initially harvested starter cell to ready-to-harvest meat tissue can be complex, but it can be classified into three broad steps: cell line development, cell manufacturing, and tissue manufacturing.[41]

---

[32] HARVEY LODISH, GROWTH OF ANIMAL CELLS IN CULTURE, MOLECULAR CELL BIOLOGY (4th ed. 2000) NCBI, https://www.ncbi.nlm.nih.gov/books/NBK21682/#A1386 [https://perma.cc/2HSY-VC3W].

[33] *See id.*

[34] *Mitosis/Cell Division*, NATURE EDUCATION, https://www.nature.com/scitable/definition/mitosis-cell-division-47/ [https://perma.cc/A693-8AWV].

[35] *See, e.g.*, Post & Hocquette, *infra* note 40, at 426, 430 (giving examples of differentiation).

[36] *Cellular Differentiation, Anatomy and Physiology*, OPEN TEXT BC, https://opentextbc.ca/anatomyandphysiology/chapter/3-6-cellular-differentiation/ [https://perma.cc/D8SB-HF5X].

[37] *Id.*

[38] Liz Specht, *Is the Future of Meat Animal-Free?,* FOOD TECHNOLOGY, 21 https://www.gfi.org/images/uploads/2018/08/LizSpechtIFTFuture.pdf [https://perma.cc/4U43-L4RP].

[39] *Id.* at 20.

[40] *See generally* M.J. Post & J.-F. Hocquette, *New Sources of Animal Proteins: Cultured Meat*, NEW ASPECTS OF MEAT QUALITY 425, 432 (Peter P. Purslow ed., 2017); *see also* Schneider, *supra* note 31, at 997–1005 (discussing challenges).

[41] Specht, *supra* note 38, at 18.

*Cell line development*. The first step in the overall process is to harvest a cell—for instance, by biopsy—from a livestock species and develop from it a cell line for biomanufacturing.[42] Cells might be selected for particular characteristics, such as nutrition, flavor, immortality, or ability to be cultured in large-scale bioreactors[43] under the desired conditions. Indeed, most cells will not divide many times even in hospital culture conditions but will instead simply die.[44] These developed cell lines serve as starters for eventual scaled-up meat-cell cultures.[45]

*Cell manufacturing*. The cell manufacturing step (also known as proliferation) essentially focuses on getting from a small quantity of cells to a very large one. [46] The process may scale a small flask's worth of cells up to large multi-thousand-liter tanks that can yield thousands of kilograms of cells.[47] The cells at the end of this process, which are likely not yet differentiated to the cell types present in the final product, may be differentiated accordingly.[48]

*Tissue manufacturing*. The tissue manufacturing step focuses on getting from a mere collection of cells to a specific physical arrangement of those cells (i.e., tissue).[49] This step may involve the use of a variety of techniques, including bioprinting, growth on three-dimensional scaffolds, and the like.[50] Finally, any aging, treatment, or maturation steps that are needed may be conducted on the assembled tissue.[51]

* * *

Note that the above steps depend on the exact nature of the final product. A highly structured product such as a steak or bacon will require much more complicated engineering than a relatively

---

[42] *Id.* at 19.

[43] For a description of bioreactors, see Mayhall, *infra* note 163, at 159.

[44] Lodish, *supra* note 32.

[45] Specht, *supra* note 38, at 18.

[46] *See* Mayhall, *infra* note 163, at 159–60.

[47] *See* Post & Hocquette, *supra* note 40, at 433–34 (discussing scaling of production).

[48] Specht, *supra* note 38, at 18.

[49] *See id.* at 19.

[50] *See, e.g.*, Norton, *supra* note 29, at 165 (explaining two major techniques of meat cultivation).

[51] B.P. Chan & K.W. Leong, *Scaffolding in Tissue Engineering: General Approaches and Tissue-Specific Considerations,* NCBI (Dec. 17, 2008) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2587658/ [https://perma.cc/CA4G-P3AJ].

unstructured product such as a chicken nugget or ground beef.[52] Accordingly, the first products on the market will most likely be unstructured.[53]

* * *

Proponents see cell-based meat as an answer to a variety of problems that plague conventional agriculture,[54] such as environmental concerns, ethical treatment of animals, and efficiency of resource exploitation, and as a way to meet increased demand for meat as the world population grows.[55] Additionally, because cell-based meat is essentially built from scratch, it offers the opportunity to fine-tune many aspects of the final product, including omitting potentially harmful compounds found naturally in meat, tweaking taste and texture, or adding new nutrients.[56] The initial goal, however, is meat that is basically identical to that which is conventionally made.[57]

A frequent criticism of cell-based meat is its cost.[58] Nevertheless, some analyses indicate that it is likely that cell-based meat can achieve cost parity with conventional meat.[59] Such cost parity, however, would require industrial-scale production.[60] Additionally, some contend that the environmental benefits of cell-based meat are overstated.[61] Other criticisms are more visceral: some view cell-based meat as "unnatural" and oppose it on that ground.[62] Others view the technology as opening the door to more ethically problematic uses, such as growing human muscle cells for

---

[52] *See, e.g.*, *id.* at 168–69 (describing the structure of chicken nuggets in detail).

[53] *See id.* at 165.

[54] For a description of modern meat production in the United States, see Mayhall, *infra* note 163, at 152–56.

[55] *E.g.*, Norton, supra note 29 at 158; Schneider, *supra* note 31, at 994 ("Some researchers estimate that in vitro meat production systems could reduce land and water resources for raising meat by up to 80% and reduce greenhouse gas emissions from raising livestock by as much as 90%."); Mayhall, *infra* note 163, at 160–61 (describing benefits of cell-based meat).

[56] Schneider, *supra* note 31, at 1005.

[57] *Id.* at 1005.

[58] *See, e.g.*, Norton, *supra* note 29, at 158 (citing high cost of in vitro meat); *id.* at 160 ("Livestock systems occupy about 30 percent of the plant's ice-free surface."); *id.* at 161 ("[A] typical pig farm of about 5,000 pigs produces waste equivalent to a small city of 20,000 people with no sewage treatment.").

[59] Liz Specht, *An Analysis of Culture Medium Costs and Production Volumes for Cell-Based Meat*, The Good Food Inst., 2 (2019), https://www.gfi.org/files/sci-tech/clean-meat-production-volume-and-medium-cost.pdf [https://perma.cc/HVP2-ZHZF].

[60] *Id.*

[61] *See* Mayhall, *infra* note 163, at 162.

[62] *See* Schneider, *supra* note 31, at 1022.

food,[63] or express concern that a rise in cell-based meat could threaten the livelihood of livestock farmers.[64]

*2. A Brief History of Cell-based Meat*

The *idea* of cell-based meat long preceded the current burst of researchers and startups. In 1931, for instance, Winston Churchill penned an essay on predictions for the distant future (i.e., 1981).[65] Among his predictions, he wrote of synthetic foods:

> Microbes, which at present convert the nitrogen of the air into the proteins by which animals live, will be fostered and made to work under controlled conditions, just as yeast is now. New strains of microbes will be developed and made to do a great deal of our chemistry for us. With a greater knowledge of what are called hormones, *i.e.,* the chemical messengers in our blood, it will be possible to control growth. 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. Synthetic food will, of course, also be used in the future. Nor need the pleasures of the table be banished. That gloomy Utopia of tabloid meals need never be invaded. The new foods will be practically indistinguishable from the natural products from the outset, and any change will be so gradual as to escape observation.[66]

This remark came nearly four decades after French chemist Pierre-Eugène-Marcellin Berthelot had opined to a reporter in 1894 that in the future, all meat would be manufactured in a

---

[63] *Id.* at 1023–24 (describing fears of so-called "victimless cannibalism," which, as it turns out, is not yet completely illegal); *see also infra* note 97 and accompanying text.

[64] Ludivine Petetin, *Frankenburgers, Risks and Approval,* 5 EUR. J. RISK REG. 168, 173 (2014).

[65] Winston Churchill, *Fifty Years Hence*, 82 STRAND MAG., 1931, at 549 [hereinafter Churchill, *Fifty Years Hence*].

[66] *Id.*

laboratory.[67] Another early visionary of cell-based meat was Willem van Eelen.[68] In World War II, at sixteen, van Eelen enlisted in the Dutch military.[69] Captured in Indonesia, he spent a substantial length of time in a Japanese POW camp.[70] There, he experienced severe starvation and witnessed animal abuse.[71] Following the war, van Eelen studied psychology, while also frequenting science-centered lectures, where these experiences prompted him to wonder about creating meat outside an animal's body.[72] Biologist Alexis Carrel had decades earlier, in 1912, demonstrated that tissue from an embryonic chicken heart could be sustained for years in a lab outside the body of an actual chicken.[73] Professors at the time viewed Van Eelen's idea as absurd—at least until the discovery of stem cells in 1981, which prompted a wave of research in cell culture.[74] Van Eelen filed patents for cell-based meat in the late 1990s, and eventually they were granted.[75] Van Eelen passed away in 2015, having lived long enough to see Mark Post's proof of concept lab-grown burger in 2013.[76]

---

[67] Maureen Ogle, *A Century Before the Lab-Grown Burger, This Chemist Imagined "Toothsome" Manufactured Food*, SLATE (Aug. 7, 2013, 12:50 PM), https://slate.com/technology/2013/08/pierre-eugene-marcellin-berthelot-s-19th-century-quest-to-create-lab-grown-food.html [https://perma.cc/4T58-EUPH].

[68] Specter, *supra* note 23.

[69] *Id.*

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] *Id.*

[74] *See id.* This wave also preceded the appearance of the idea in science fiction (in a generally pessimistic representation); *see also* Kerry Halladay, *Kerry's Comments: Fake Meat—Science Fiction to Science Fact*, W. LIVESTOCK J. (June 6, 2019), https://www.wlj.net/opinion/kerry/kerry-s-comments-fake-meat-science-fiction-to-science-fact/article_ffb86c38-886b-11e9-8ad5-77dba8822a90.html [https://perma.cc/6VEY-MH8L]. Other science fiction references are more positive, as in the utopian *Star Trek*, *see Charlie X (Episode)*, MEMORY ALPHA, https://memory-alpha.fandom.com/wiki/Charlie_X_(episode) [https://perma.cc/73UR-J7T4]; *see also* Cannomore, *Star Trek: The Next Generation*, *The Dietary Requirements of a Star Fleet Officer*, YOUTUBE (Sept. 11, 2008), https://www.youtube.com/watch?v=sS7NRtEJBcA [https://perma.cc/9CMV-TGBX].

[75] Specter, *supra* note 68.

[76] *"Godfather of Cultured Meat" Willem Van Eelen Passes Away at 91*, NEW HARVEST (Apr. 2, 2015), https://www.new-harvest.org/_godfather_of_cultured_meat_willem_van_eelen_passes_away [https://perma.cc/2V68-7XQ2].

Other conventional-meat substitutes came first:[77] for instance, at the turn of the twentieth century, Dr. John Harvey Kellogg (of cereal fame) introduced, after much experimentation, Protose, an "insipid mixture of nuts and gluten" that was claimed to "resemble[] potted veal or chicken" but tasted, basically, like nuts.[78] Protose was not terribly successful.[79] Nor was the "artificial meat" made by Jean Effront in 1912 by washing and compressing various brewery and distillery wastes and dousing them with sulfuric acid.[80] (That said, rats and workmen gained weight when eating it, and some physicians deemed it "superior to beef.")[81] Later, though, soy-based burgers came into vogue in the 1970s and 1980s, led by MorningStar Farms and Gardenburger, which enjoyed greater success due to improved taste and arguably better marketing.[82] A second wave of veggie burgers followed.[83] More recently, quite realistic plant-based meat alternatives like Beyond Meat and the Impossible burger have exploded in popularity in the last few years.[84]

Early patents for cell-based meat were filed in the late 1990s and early 2000s and expired before any such products came to market.[85] Around 2000, researchers at Touro College in New

---

[77] *See generally,* Deena Prichep, *The Rise of Mock Meat: How Its Story Reflects America's Ever-Changing Values*, NPR: THE SALT (Sept. 2, 2017, 7:00 AM), https://www.npr.org/sections/thesalt/2017/09/02/547899191/the-rise-of-mock-meat-how-its-story-reflects-americas-ever-changing-values [https://perma.cc/5EGG-TDDU].

[78] Tad Friend, *supra* note 9. Protose was discontinued by the Kellogg company around 2000. *See* Sarah Lohman, *History Dish Mondays: Protose*, FOUR POUNDS FLOUR (Feb. 22, 2009), http://www.fourpoundsflour.com/history-dish-mondays-protose/ [http:/perma.cc/ E5HJ-2WTV]. Some vegan enthusiasts, however, describe a similar recipe. *Id.*

[79] Jackie Mansky, *We're Entering a New Age of Meatless Meat Today. But We've Been Here Before*, SMITHSONIAN MAGAZINE (April 25, 2019), https://www.smithsonianmag.com/arts-culture/turn-century-meatless-meat-180972042/ [https://perma.cc/Q8FZ-KT8F].

[80] *See* Ogle, *supra* note 67. It is perhaps telling that Effront argued, somewhat defensively, "It would be a hundred times better if foods were without odor or savor." *Id.* That said, as strange as Effront's acid-treatment process sounds, acid hydrolysis of plant matter is commonly used to make savory foods on an industrial scale.

[81] *Id.*

[82] Friend, *supra* note 9; Prichep, *supra* note 77.

[83] Prichep, *supra* note 77.

[84] *See, e.g.*, Annie Lowrey, *What's Different About the Impossible Burger?*, ATLANTIC (Sept. 23, 2019), https://www.theatlantic.com/ideas/archive/2019/09/vegan-food-goes-mainstream/598558/ [https://perma.cc/3CYC-EJ8X] ("Beyond's chicken strips taste and shred a lot like chicken; its burgers and its sausages are, if not quite indistinguishable from real meat, awfully close. The same goes for … the Impossible Burger.").

[85] *See*, *e.g.*, U.S. Patent No. 7,270,829 B2 (to Willem Frederik van Eelen) (claiming priority to 1997); U.S. Patent No. 6,835,390 B1 (to Jon Vein) (claiming priority to 2000).

York produced edible fish filets from goldfish cells, and in 2001, NASA began generating lab-grown meat from turkey cells.[86] The fish filets were fried after being dipped in olive oil with lemon, garlic, and pepper, but they were not actually tasted (at least according to the Touro researchers).[87] In 2003, researchers from Harvard Medical School grew frog skeletal muscles over a biopolymer in the shape of a steak.[88]

In 2008, PETA offered a $1 million prize to the first company to introduce acceptable lab-grown chicken meat.[89] And by 2009, reflecting scientific enthusiasm despite the lack of working prototypes, *Time* magazine designated cultured meat among the "50 best inventions of 2009."[90] In 2019, four companies took part in an experiment to grow meat on the Russian segment of the International Space Station.[91] Numerous academic lab groups have also conducted related research.[92]

The rise in enthusiasm for cell-based meat draws not only on increasing public concern for environmentalism, animal welfare or public health, but also on public fascination with experimental foods and molecular gastronomy. Consider, for instance, Bistro In Vitro—a fictional restaurant with a website showcasing the kinds

---

[86] Rebecca Rupp, *Meat, Shmeat*, NAT'L GEOGRAPHIC: THE PLATE (Sept. 16, 2014), https://www.nationalgeographic.com/culture/food/the-plate/2014/09/16/meat-shmeat/ [https://perma.cc/2YUD-BNMQ]; Ian Sample, *Fish Fillets Grow in Tank*, NEWSCIENTIST (Mar. 20, 2002), https://www.newscientist.com/article/dn2066-fish-fillets-grow-in-tank/ [https://perma.cc/SP7D-6X5W].

[87] Sample, *supra* note 86.

[88] *Disembodied Cuisine*, TISSUE CULTURE & ART PROJECT, http://lab.anhb.uwa.edu.au/tca/disembodied-cuisine/ [https://perma.cc/Q74N-CEJ3]. The frog steak was part of an exhibition in France titled "Disembodied Cuisine." *Id.* The steak, which was grown alongside obviously happy frogs as part of an art exhibit, was cooked and eaten on the last day of the exhibition. *Id.* The frogs were not. They were released, purportedly, "to a beautiful pond in the local botanical gardens." *Id.*

[89] *PETA's 'In Vitro' Chicken Contest*, PETA, https://www.peta.org/features/vitro-meat-contest/ [https://perma.cc/WJ3U-8WA4]. The prize expired in 2014 unclaimed, but PETA characterized the endeavor as a "smashing success," referencing the advances in science in the interim. *Id.*

[90] *The 50 Best Inventions of 2009: Meat Farms*, TIME (2009), http://content.time.com/time/specials/packages/article/0,28804,1934027_1934003_1933982,00.html [https://perma.cc/E5L8-TLM7].

[91] *See* Brooke Sunness, *Cell Based Tech Weekly – Future Meat Raises $14M, Space Food, Meatech 3D Stem Cell Printing, WildType Raises $12.5M*, CELL BASED TECH (Oct. 12, 2019), https://cellbasedtech.com/2019/10/cell-based-tech-weekly-future-meat-raises-14m-space-food-meatech-3d-stem-cell-printing-wildtype-raises-12m [https://perma.cc/7S4C-J6V2].

[92] *E.g.*, Norton, *supra* note 55, at 165 (describing examples in the Netherlands, Sweden, and Norway).

of dishes that are envisioned once cell-based meat becomes mainstream.[93] Bistro In Vitro, which premiered in 2015, allows users to create a "digital reservation" and select their own menu from a host of fancifully imagined (though, in some instances, perhaps somewhat horrifying) products presumably only available through advances in cell technology: dodo nuggets,[94] origami made from cultured crane meat,[95] "meat fruit,"[96] and cubes of meat made from the stem cells of various celebrities.[97] The Bistro followed a 2014 fictional cookbook featuring "45 lab grown meat recipes you cannot cook yet."[98]

Still, you cannot yet buy cell-based meat in a store.[99] As to the development of actual products, the industry is mostly aspirational at the moment.[100] But there have been several prominent proof-of-concept examples, and several companies have announced the intent to release products commercially in the next few years.[101]

The first public demonstration of cell-based meat came in 2013 in the form of a lab-grown burger prepared by Mark Post's

---

[93] BISTRO IN VITRO, https://bistro-invitro.com/en/welcome-to-bistro-in-vitro/ [https://perma.cc/CSS8-YLPX]; *see also* Tove Danovich, *Bistro In Vitro: A Virtual Playground to Ponder the Future of Meat*, NPR: THE SALT (May 15, 2016, 1:56 PM), https://www.npr.org/sections/thesalt/2015/05/15/406725711/bistro-in-vitro-a-virtual-playground-to-ponder-the-future-of-meat [https://perma.cc/HN43-J8PX] (Bistro In Vitro serves "food for thought.").

[94] *Dodo Nuggets*, BISTRO IN VITRO, https://bistro-invitro.com/en/dishes/dodo-nuggets/ [https://perma.cc/EK8X-TY36].

[95] *Crane Origami*, BISTRO IN VITRO, https://bistro-invitro.com/en/dishes/crane-origami/ [https://perma.cc/CK6Q-TJJW].

[96] *Meat Fruit*, BISTRO IN VITRO, https://bistro-invitro.com/en/dishes/meat-fruit/ [https://perma.cc/6MNF-4XJP] ("In this variation on a classic fruit tart, the crème pâtissière has been replaced with a savory sauce. This turns our meat-berry tart into a savory-sweet dessert that begins with an intense hit of beef and finishes with the sweet taste of blueberries.").

[97] Dipped in a whiskey glaze, naturally. *Celebrity Cubes*, BISTRO IN VITRO, https://bistro-invitro.com/en/dishes/celebrity-cubes/ [https://perma.cc/G37G-JR2H].

[98] *The In Vitro Meat Cookbook*, MENSVOORT, https://www.mensvoort.com/work/the-in-vitro-meat-cookbook/ [https://perma.cc/87FS-7KAK].

[99] Brian Kateman, *Will Cultured Meat Soon Be A Common Sight In Supermarkets Across The Globe?,* FORBES (Feb 17, 2020 8:58 AM) https://www.forbes.com/sites/briankateman/2020/02/17/will-cultured-meat-soon-be-a-common-sight-in-supermarkets-across-the-globe/#122778347c66 [https://perma.cc/BJQ8-B4Q8].

[100] *Id.*

[101] *Id.*

laboratory at Maastricht University in the Netherlands.[102] There, chef Richard McGeown seared the burger, which had been made from lab-grown stem cells at a cost of about $325,000.[103] The estimated cost for an equivalent burger dropped to $11 two years later, due to advances in stem cell technology.[104] Two food critics sampled it; one, Hanni Rützler, characterized it as "close to meat," although the burger, which lacked fat, was disappointingly dry.[105]

Memphis Meats premiered what it refers to as the world's first cell-based meatball in 2016 and the world's first cell-based poultry in 2017.[106] By 2019, JUST had also publicly announced (and a journalist had sampled) a proof-of-concept chicken nugget.[107]

Wild Type debuted cell-cultured Coho salmon at a private even in June 2019, showcasing the fish in ceviche, tartare, and sushi.[108] Likewise, BlueNalu in December 2019 put on another early public demonstration of cell-based seafood.[109] The event, in San Diego, saw the company's chef preparing a variety of dishes featuring the cell-based yellowtail amberjack, including tacos,

---

[102] Jenny Splitter, *Please Don't Call This Cultured Nugget "Lab Meat,"* POPULAR MECHANICS (Dec. 20, 2019), https://www.popularmechanics.com/science/a30221344/cultured-lab-meat/ [https://perma.cc/5T4G-U863].

[103] *Id.*

[104] BEC Crew, *Cost of Lab-Grown Burger Patty Drops from $325,000 to $11.36*, SCIENCEALERT (Apr. 2, 2015), https://www.sciencealert.com/lab-grown-burger-patty-cost-drops-from-325-000-to-12 [https://perma.cc/UF2P-CKGH].

[105] Splitter, *supra* note 102.

[106] *E.g.*, Mike Pomranz, *This Lab-Grown Meatball Only Took 3 Weeks and Cost $18,000 to Make*, FOOD & WINE (Feb. 4, 2016), https://www.foodandwine.com/fwx/food/lab-grown-meatball-only-took-3-weeks-and-cost-18000-make [https://perma.cc/662K-MAB6]; Leanna Garfield, *A San Francisco Startup Just Created the World's First Lab-Grown Chicken*, BUSINESS INSIDER (Mar. 15, 2017, 12:20 PM), https://www.businessinsider.com/memphis-meats-chicken-lab-grown-2017-3 [https://perma.cc/NFJ7-X75M].

[107] Olga Khazan, *The Coming Obsolescence of Animal Meat*, ATLANTIC (April 16, 2019), https://www.theatlantic.com/health/archive/2019/04/just-finless-foods-lab-grown-meat/587227/ [https://perma.cc/B2GL-EEMS].

[108] *Cell Based Tech Weekly – Amyris Announces Partnership with Berkeley Lights, Wild Type Serves Coho Salmon in Portland, Ginkgo Bioworks Invests in Synlogic*, CELL BASED TECH (June 14, 2019), https://cellbasedtech.com/2019/06/cell-based-tech-weekly-amyris-announces-partnership-with-berkeley-lights-wild-type-serves-coho-salmon-in-portland-gingko-bioworks-invests-in-synlogic [https://perma.cc/NF2Q-KSCU]; *An Early Taste of Wild Type Salmon*, MEDIUM (June 12, 2019), https://medium.com/@wild_type/salmon-dbfd318e5873 [https://perma.cc/FA8C-4G7X].

[109] Julia John, *BlueNalu Makes a Splash with Groundbreaking Cultivated Yellowtail*, GOOD FOOD INST. (Dec. 19, 2019), https://www.gfi.org/blog-bluenalu-cultivated-yellowtail [https://perma.cc/E8LV-HN8B].

bisque, poke, and kimchi.[110] According to BlueNalu, the product "performs the same as a conventional fish fillet in all cooking applications."[111]

That said, according to some experts, it is unlikely that a product release will happen in 2020.[112] Nonetheless, it appears extremely likely that cell-based meat will be available for purchase within the next handful of years.[113] Despite several companies having passed publicly announced target dates for product launches, a few remain optimistic for the upcoming year.[114] JUST, for instance, intends a 2020 small-scale launch of $50-each chicken nuggets made from cell-based chicken and mung bean protein isolate.[115] And Future Meat intends to sell "hybrid" products by 2021 that blend lab-grown fat cells with plant protein.[116]

### *B. The (Cultivated) Meat Market*

#### *1. Current Major Producers*

Cultivated-meat companies did not proliferate until quite recently, with most such companies having been founded in the last two years.[117] By the end of 2018, there were 27 known cultivated-meat companies.[118] Many are in the seed-funding round; none have brought a product yet to market.[119] Geographically, most of these companies are based in the United

---

[110] *Id.*

[111] *Id.*

[112] Michael Dent, *What Will Happen to the Cultured Meat Industry in 2020?*, IDTECHEX (Dec. 17, 2019), https://www.idtechex.com/en/research-article/what-will-happen-to-the-cultured-meat-industry-in-2020/19210 [https://perma.cc/8MTJ-ZTYP].

[113] *Id.*

[114] *Cell Based Tech Weekly – JUST Preps $50 Nuggets, BASF Launches Breast Milk Supplement, Agronomics Investing Strikes Again*, CELL BASED TECH (Nov. 2, 2019), https://cellbasedtech.com/2019/11/cell-based-tech-weekly-just-preps-50-nuggets-basf-launches-breast-milk-supplement-agronomics-investing-strikes-again [hereinafter *Cell Based Tech Weekly Nov. 2, 2019*] [https://perma.cc/HLY7-DF6G].

[115] *Id.*

[116] Amelia Lucas, *Lab-Grown Meat Start-Up Raises $14 Million to Build Production Plant*, CNBC (Oct. 10, 2019), https://www.cnbc.com/2019/10/10/future-meat-technologies-a-lab-grown-meat-start-up-raises-14-million-dollars.html [https://perma.cc/F463-7SVT].

[117] Brianna Cameron et al., *State of the Industry Report: Cell-Based Meat,* GOOD FOOD INST., 5 (2019), https://www.gfi.org/non-cms-pages/splash-sites/soi-reports/files/SOI-Report-Cell-Based.pdf [https://perma.cc/3U72-34VD].

[118] *Id.* at 5.

[119] *See id.* at 3.

States, but some hail from Israel, the Netherlands, Spain, and Japan, among other countries.[120] Investment is on the upswing, with $80 million invested across the industry in 2019 and higher amounts expected in 2020.[121] In contrast, investment funding industry-wide was around $35 million in 2018, just under $20 million in 2017, and around $2 million in 2016.[122] Prominent individual investors include Bill Gates, Elon Musk, and Richard Branson.[123]

The following table lists known cultivated-meat companies around the world as of January 2020:[124]

| Company | Country | Product |
|---|---|---|
| Aleph Farms | Israel | Meat (steak). |
| Appleton Meats | Canada | Meat (beef). |
| Artemys Foods | United States | Meat. |
| Avant | China | Meat. |
| Balletic Foods | United States | Meat. |
| Biftek.co | Turkey | Meat (beef). |
| Biofood Systems | Israel | Meat (beef). |
| BlueNalu | United States | Seafood (yellowtail). |
| Bond Pet Foods | United States | Pet food (chicken). |
| ClearMeat | India | Meat (chicken). |
| Cubiq Foods | Spain | Cell based animal fats. |
| Finless Foods | United States | Seafood (bluefin tuna). |

[120] *Id.* at 7.

[121] Dent, *supra* note 112; *see also Lab Grown Meat Stocks*, CELL BASED TECH (Dec. 22, 2019), https://cellbasedtech.com/2019/12/lab-grown-meat-stocks [https://perma.cc/9D5A-JNCQ].

[122] Dent, *supra* note 112.

[123] Halladay, *supra* note 74.

[124] Cameron et al., *supra* note 117; *Lab Grown Meat Companies*, CELL BASED TECH, https://cellbasedtech.com/lab-grown-meat-companies [https://perma.cc/C9ZV-HMYA] (This is a rapidly evolving sector, and so this list may not necessarily capture every company); *Our Story*, ARTEMYS, https://artemysfoods.com/#ourstory (last visited May 12, 2020) [https://perma.cc/M3UL-RVYE].

| | | |
|---|---|---|
| Fork & Goode | United States | Undisclosed. |
| Future Meat (FM) Technologies | Israel | Meat (chicken). |
| Gourmey | France | Meat (foie gras). |
| Higher Steaks | UK | Beef. |
| Integriculture | Japan | Meat (foie gras chicken). |
| JUST | United States | Meat (chicken, wagyu beef). |
| Meatable | Netherlands | Meat (beef). |
| Memphis Meats | United States | Meat (beef, chicken, duck). |
| Mission Barns | United States | Meat (duck, chicken, pork). |
| Mosa Meat | Netherlands | Meat (beef). |
| New Age Meats | United States | Meat (pork). |
| SeaFuture | Canada | Seafood. |
| Shiok Meats | Singapore | Seafood. |
| SuperMeat | Israel | Meat (chicken). |
| Suprême | France | Meat (foie gras). |
| VOW | Australia | Meat (kangaroo). |
| Wild Earth | United States | Pet Food (mouse). |
| Wild Type | United States | Seafood (salmon). |

Beyond simply producers themselves, a number of firms have partnered with cultivated-meat companies for research and development purposes.[125] For example, Merck's venture-capital arm M Ventures has invested in Mosa Meats, and Tyson's venture-capital arm Tyson Ventures has invested in Memphis Meats and Future Meat Technologies.[126]

Other companies have been founded to develop technologies that support cell-based meat development—technologies such as cell media, cell and protein characterization technology, cell

[125] *Lab Grown Meat Stocks*, *supra* note 121.
[126] Cameron et al., *supra* note 117, at 9, 10.

scaffolds, software, and more.[127] The growth of the cell-based meat industry will require the accompanying growth of companies dedicated to the production of such technologies.[128]

*2. Nonprofits and Advocacy Organizations*

The cell-based meat industry includes a number of important nonprofits and lobbying groups. Among the nonprofits is, for instance, the international Cellular Agriculture Society ("CAS").[129] CAS uses donations to "advance cellular agriculture" and partners with companies pursuing cellular agriculture applications in meat, seafood, eggs, dairy, leather, silk, wildlife products, and gelatin.[130] CAS lists a large number of partners on its site, including meat companies SuperMeat and JUST and fish companies Finless Foods and Wild Type.[131]

The industry's first American lobbying group is the Alliance for Meat, Poultry, and Seafood Innovation ("AMPS Innovation"), which was announced August 29, 2019 and includes founding members JUST, Memphis Meats, Finless Foods, BlueNalu, and Fork & Goode.[132] Previously, the interests of these companies were primarily represented by DC-based nonprofit The Good Food Institute ("GFI")—an organization that also advocates on behalf of plant-based food organizations.[133]

Along these lines, academic researchers have begun to collaborate with cultivated-meat companies. The availability of research grant money has facilitated this; for instance, through GFI's Competitive Research Grant and various grants through New Harvest, a donor-funded research institute dedicated to the

---

[127] *Id.* at 10.

[128] *See*, *Lab Grown Meat Stocks*, *supra* note 121 (provides a list of such companies in the cell-based meat industry).

[129] CELLULAR AGRIC. SOC'Y, https://www.cellag.org/ [https://perma.cc/6V6F-CSVQ].

[130] *Id.*

[131] *Partners*, CELLULAR AGRIC. SOC'Y, https://www.cellag.org/partners/ [https://perma.cc/UT4N-B3X2].

[132] Chase Purdy, *The Leading US Cell-Based Meat Startups Just Forged an Alliance*, QUARTZ (Aug. 29, 2019), https://qz.com/1698237/cell-cultured-meat-companies-now-have-a-lobbying-group/ [https://perma.cc/D364-DCHC]; *Our Mission*, ALLIANCE FOR MEAT, POULTRY, SEAFOOD INNOVATION, https://ampsinnovation.org/ [https://perma.cc/P3M4-KS7Z].

[133] Purdy, *supra* note 132.

field of cellular agriculture.[134] Nonetheless, the amount of funding remains relatively low: New Harvest, for instance, has awarded only $2.2 million in research funding since 2008.[135]

### *C. Regulatory Context: USDA and FDA*

The development of cell-based meat as a potential human food has resulted in considerable debate about *how* to regulate and *who* should regulate these products. Under the FDA-USDA Formal Agreement, dated March 7, 2019, the key regulators will be the United States Department of Agriculture Food Safety and Inspection Service ("USDA-FSIS") and the U.S. Food and Drug Administration ("FDA").[136] Press and commentary calls this document the "memorandum of understanding" ("MOU"), consistent with previous FDA memoranda, although the agreement itself does not use that term.[137] The Formal Agreement, discussed in detail further below, draws on existing precedents in American food law. Under long-standing federal statutes, USDA-FSIS oversees meat, poultry, and certain egg products.[138] Meanwhile, FDA exercises jurisdiction over all other food products, including the safety of ingredients used in meat and poultry products.[139] Other agencies, such as the Environmental Protection Agency ("EPA") and Centers of Disease Control and Prevention ("CDC") also have an auxiliary role in food regulation, but they are unlikely to play a major role in the regulation of cell-based meat.[140]

---

[134] Cameron et al., *supra* note 117.

[135] *Current Research Projects*, NEW HARVEST, https://www.new-harvest.org/current_research_projects; Dolgin, *supra* note 14.

[136] *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, U.S. FOOD & DRUG ADMIN. (Mar. 7, 2019), https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell [https://perma.cc/WQ5G-P25F].

[137] *Id.*

[138] *See* Federal Meat Inspection Act, 21 U.S.C. § 621 (2020); Poultry Products Inspection Act, 21 U.S.C. § 451 (2020); Egg Production Inspection Act (EPIA), 21 U.S.C. § 1031 (2020).

[139] *See* Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 (2020).

[140] INST. OF MEDICINE AND NAT'L RES. COUNCIL, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION, 26-28, (1998).

*1. USDA*

A product qualifying as "meat" under the USDA's definition triggers USDA jurisdiction. The USDA defines "meat" as:

> [t]he part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing.[141]

Under the USDA's amenability policy, any product that enters interstate commerce containing greater than 3 percent raw meat or 2 percent cooked meat falls under the jurisdiction of USDA-FSIS.[142] Since cell-based meat is produced by stem cells sourced from the species of livestock and authorized parts of the animals listed above, cell-based meat may satisfy the USDA's current definition of meat[143] and thus trigger USDA-FSIS jurisdiction. Analogous reasoning applies to fitting poultry produced with cell-culture technology within USDA's definition for "poultry product."[144]

For products under USDA-FSIS jurisdiction, oversight includes inspection of all animals and carcasses during the harvest

---

[141] 9 C.F.R. § 301.2 (2020) (For USDA's purposes, meat does not include "the muscle found in the lips, snout, or ears" and the definition specifies that meat may not include "significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia); *see also* 21 U.S.C. § 453(e) (2020) (Analogously, poultry is defined as "any domesticated bird, whether live or dead").

[142] Food Safety and Inspection Service, *Food Standards and Labeling Policy Book*, USDA, (Aug. 2005) https://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccf-a2d5-b95a128f04ae/Labeling-Policy-Book.pdf?MOD=AJPERES [https://perma.cc/LMK8-MCV4]; *see also* 9 C.F.R. § 381.15(a)(1) (2020) (listing out similar requirements for poultry).

[143] 21 U.S.C. § 601(j) (2020); *see* Sylvester, *infra* note 157 (There is an alternative argument that cell-based meat would qualify as "meat food product" under the FMIA since a reasonable consumer might perceive cell-based meat to be a product of the meat industry).

[144] 21 U.S.C. § 453(f) (2020).

activity,[145] pre-approval of labeling for all meat products,[146] and Hazard Analysis and Critical Control Point ("HACCP") requirements to manage foodborne illness risks.[147] Additionally, in order to satisfy both the Federal Meat Inspection Act ("FMIA") and the Poultry Products Inspection Act ("PPIA"), USDA-FSIS must inspect the meat and poultry products before the products are marketed in interstate commerce in order to ensure that they are "safe," "wholesome," and properly labeled.[148] The FDA-USDA Formal Agreement makes clear that the USDA will exercise inspection and labeling oversight for cell-based meat upon harvest from the bioreactor.[149]

*2. FDA*

While cell-based meat may qualify as "meat" as the USDA currently defines it,[150] FDA also has significant experience in regulating food, including novel foods.[151] FDA exercises jurisdiction over most food products pursuant to the FDCA.[152] Importantly, the FDCA authorizes FDA to oversee the safety of all food ingredients used in both FDA- and USDA-regulated foods.[153] In addition to food, FDA exercises jurisdiction over biologics, including vaccines; blood and blood products; cellular and gene therapy products; and tissue and tissue products.[154] Accordingly, FDA has been the lead federal agency involved in determining the safety of new biotechnological approaches to foods, including

---

[145] Food Safety and Inspection Service, *Slaughterhouse Inspection 101*, USDA (Aug. 09, 2013), https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/slaughter-inspection-101/slaughter-inspection-101 [https://perma.cc/Z93J-FS62]; 21 U.S.C. § 604 (2020).

[146] 21 U.S.C. §§ 601(n)–(p).

[147] 21 U.S.C. § 350(g) (1994); *See* Sylvester, *infra* note 157.

[148] 21 U.S.C. § 451 (1968).

[149] *USDA–FDA Memorandum of Understanding*, *supra* note 136.

[150] Sylvester, *infra* note 157.

[151] *See, e.g.*, *Food from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-ingredients-packaging/food-new-plant-varieties [https://perma.cc/MH5C-AE4].

[152] Sylvester, *infra* note 157.

[153] *Id.*

[154] *CBER Product Jurisdiction*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/cber-product-jurisdiction [https://perma.cc/H258-B7A9].

genetically modified crops and animal cloning.[155] FDA noted that "it seems reasonable to think that cultured meat, if manufactured in accordance with appropriate safety standards and all relevant regulations, could be consumed safely."[156] Likewise, FDA previously positioned itself to take a leading role in cell-based meat discussions by publicly commenting on its "extensive experience applying its existing authority flexibly and effectively to rapidly evolving areas of technological innovation such as plant biotechnology."[157] FDA also publicly stated that it looks forward to sharing its "experiences in evaluating and ensuring the safety of novel technologies in the food sector . . . while . . . also discuss[ing] these issues with and gather[ing] relevant data and information from stakeholders."[158]

A key difference between FDA and USDA-FSIS food regulatory oversight is the level of premarket inspection. For FDA, the Food Safety Modernization Act ("FSMA") mandates inspection frequency based on *risk* for food facilities, in stark contrast to USDA-FSIS's requirement for physical presence of inspectors during an establishment's operating hours regardless of risk.[159]

---

[155] *See, e.g.*, *Consumer Info About Food from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-new-plant-varieties/consumer-info-about-food-genetically-engineered-plants (last updated Jan. 4, 2018) [https://perma.cc/2ZQA-TT8N].*; Animal Cloning, infra* note 267; Larisa Rudenko & John C. Matheson, *The US FDA and Animal Cloning: Risk and Regulatory Approach*, 67 THERIOGENOLOGY 1 (2007); Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2217 (2004).

[156] Charlotte Hawks, *How Close Are We to a Hamburger Grown in a Lab?*, CNN (March 8, 2018, 2:23 PM), https://www.cnn.com/2018/03/01/health/clean-in-vitro-meat-food/index.html [https://perma.cc/A4TM-GFEA].

[157] *Public Meeting on Foods Produced Using Animal Cell Culture Technology*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-foods-produced-using-animal-cell-culture-technology [hereinafter *July 2018 FDA Meeting*]; 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/M8K5-TZBH].

[158] *Id.*

[159] 21 U.S.C. § 606; *see* Sylvester, *infra* note 215.

### *3. Cooperative Regulation by Agreement of USDA and FDA*

#### *(a) The Regulatory Conversation*

FDA hosted two public meetings in July and October 2018 focusing on cell-based meat. The first meeting, on July 12, focused on safety considerations and marked the first instance of the US government formally engaging stakeholders on cellular-agriculture.[160] At the meeting, USDA Secretary Sonny Perdue and then-FDA Commissioner Scott Gottlieb announced the intent of the two agencies to cooperatively regulate cell-based meat.[161]

This reflected a change in the previous tension between the two agencies, who had each publicly opined on their own jurisdiction over cell-based meat and poultry.[162] Various commentators had also previously expressed conflicting opinions about which agency—or both—would be the best regulator of this new technology.[163]

In addition to agency presentations, the meeting featured input by Memphis Meats and New Harvest, among others.[164] FDA specifically sought input on "variations in manufacturing methods [that] would be relevant to safety for foods produced by animal cell culture technology," the safety of "substances [that] would be used in the manufacture of foods produced using animal cell culture technology," the existence of "potential hazards associated with production of foods using animal cell culture technology different from those associated with traditional food production/processing," the accompanying "need for unique control measures to address potential hazards," and, generally, any "considerations specific to animal cell culture technology [that] would be appropriate to include in evaluation."[165]

The second meeting was jointly hosted by FDA and the USDA, and took place on October 23 and 24 in 2018, focusing on

---

[160] *July 2018 FDA Meeting*, *supra* note 137.

[161] Sylvester, *supra* note 160.

[162] 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/TJ7A-VUMN]; Sylvester, *supra* note 160.

[163] *See, e.g.*, Schneider, *supra* note 31 (recommending FDA and USDA regulation); Taylor A. Mayhall, *The Meat of the Matter: Regulating a Laboratory-Grown Alternative*, 74 FOOD & DRUG L.J. 151 (2019) (recommending USDA regulation).

[164] *July 2018 FDA Meeting*, *supra* note 160.

[165] *Id.*

the "potential hazards, oversight considerations, and labeling of cell cultured food products derived from livestock and poultry tissue."[166] At this meeting, USDA and FDA officials presented on their regulatory roles and capabilities in order to determine what might be the most appropriate oversight framework.[167] Industry representatives and other stakeholders also participated.[168]

### *2. The FDA–USDA Cooperative Regulatory Agreement*

On November 16, 2018, FDA and the USDA issued an informal joint statement on the details of their regulation of cell-based meat from livestock and poultry cells.[169] In that statement, the agencies announced that they would jointly oversee the production of cell-based meat from livestock and poultry via a "joint regulatory framework" in which FDA is tasked with oversight of cell collection, cell banks, and cell growth and differentiation (i.e., the first stages of cell-based meat production).[170] Under that agreement, the USDA then exercises regulatory oversight at the cell harvest stage and oversees production and labeling of food products.[171] The announcement also noted that the agencies intend to develop "robust collaboration and information sharing."[172]

The agreement, the agencies emphasized, would capitalize on FDA's "experience regulating cell-culture technology and living biosystems" and the USDA's "expertise in regulating livestock and poultry products for human consumption."[173] In this sense, the FDA–USDA agreement constitutes a common-sense, pragmatic

---

[166] *Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/joint-public-meeting-use-cell-culture-technology-develop-products-derived-livestock-and-poultry (last updated Oct. 26, 2018) [hereinafter *October 2018 Joint USDA-FDA Meeting*] [https://perma.cc/3AGQ-45VZ].

[167] *Id.*

[168] *Id.*

[169] *Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry*, U.S. DEP'T AGRIC. (Nov. 16, 2018), https://www.usda.gov/media/press-releases/2018/11/16/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb [hereinafter *Perdue–Gottlieb Statement*] [https://perma.cc/6JTS-6FK4].

[170] *Id.*

[171] *Id.*

[172] *Id.*

[173] *Id.*

approach. Importantly, as part of the November 2018 announcement, the agencies expressed the belief that no specific legislation appeared necessary for cell-based meat.[174] However, we now know that new labeling regulations are on the horizon. In a webinar released by the USDA and FDA on July 31, 2020, USDA announced that the Agency intends to develop regulatory requirements "to ensure the truthful labeling of food products derived from the cultured cells of livestock and poultry" and will work with FDA "to develop joint principles for the labeling of cell cultured food products under their respective jurisdictions."[175]

Following on the November 2018 announcement, the FDA and USDA entered into a formal, joint published final agreement released on March 7, 2019.[176] The formal agreement stipulates that the FDA will oversee cell collection and propagation up to harvesting as a cell-based meat, at which point USDA-FSIS becomes the responsible agency.[177] This is not the first time FDA and USDA have shared regulatory jurisdiction; in fact, the FDA and USDA have a long history of cooperatively working together.[178]

The March 7, 2019 agreement delineates the following roles for the two agencies for cultivated-meat products:[179]

| FDA | USDA | Both |
|---|---|---|
| 1. "Conduct premarket consultation as to production materials, processes," and manufacturing controls. | 1. Require establishments that harvest, process, packages, or labels cells for cell-based meat and poultry to obtain a grant of inspection by USDA-FSIS.<br>2. Inspect those establishments.<br>3. Require preapproval of product labeling. | 1. Coordinate oversight transfer from FDA to the USDA at the time of cell harvesting.<br>2. Develop a more detailed |

[174] *Id.*

[175] FDA and USDA Roles and Responsibilities for Cultured Animal Cell Human and Animal Food Products, FDA CFSAN, (July 24, 2020) https://www.youtube.com/watch?v=j4DCAx0EhYM [https://perma.cc/DE6Z-BVDP].

[176] *USDA–FDA Memorandum of Understanding*, *supra* note 136.

[177] *Id.*

[178] *See* Sylvester, *infra* note 215.

[179] *USDA–FDA Memorandum of Understanding*, *supra* note 136.

| | | |
|---|---|---|
| 2. Oversee cell collection and cell banks.<br>3. "Oversee proliferation and differentiation of cells through harvest."<br>4. Ensure compliance of covered entities with FDA requirements, including facility registration, CGMP and preventive controls regulation, and requirements applicable to food components.<br>5. Develop requirements for cell banks and cell-culture facilities as needed.<br>6. Inspect and take enforcement actions regarding cell banks and cell- | 4. Develop additional requirements for labeling for safety and accuracy.<br>5. Conduct enforcement actions to prevent adulterated/misbranded products from being in commerce.<br>6. "Share information with HHS-FDA." | joint framework or procedure for cell harvesting.<br>3. Identify if statutes or regulations need to be changed.<br>4. Meet and collaborate regularly.<br>5. Develop joint product labeling and claim principles.<br>6. Cooperate as needed, to investigate food-safety issues.<br>7. Notify the other party if unable to perform designated role. |

| | | |
|---|---|---|
| culturing facilities.<br>7. "Share information with the USDA-FSIS." | | |

The agreement applies to "human food produced using animal cell culture technology, derived from cell lines of USDA-amenable species and required to bear a USDA mark of inspection."[180] Thus, the USDA's role only applies where the resulting products are those that are required to bear the USDA mark of inspection: beef, chicken, and the like.[181] The agreement also does not try to expand the USDA's jurisdiction, and so the USDA would not be involved, then, in cell-based seafood—for which FDA is charged with exercising inspection and labeling oversight.[182] Likewise, the USDA's role extends only to human-food products.[183] Left outside this example of regulatory clarity, then, are pet foods and cell-cultured wild game.[184]

As pertains to food safety, the agreement emphasized the role of FDA in "ensuring that food is not adulterated . . . , including regulating food ingredients used during the production of meat, poultry, and egg products" as well as "conduct[ing] inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by USDA-FSIS."[185] The agreement also referenced the USDA's responsibilities in implementing and enforcing the FMIA, PPIA, and Egg Products Inspection Act ("EPIA"), including "plac[ing] inspectors in meat and poultry slaughter and processing establishments and egg products processing plants," as well "reinspect[ing] 100 percent of imported meat, poultry, and egg products" and "enforce[ing] the . . . adulteration provisions of its authorizing statutes."[186]

---

[180] *Id.*
[181] *Id.*
[182] *Id.*
[183] *Id.*
[184] *Lab Grown, supra* note 121.
[185] *USDA–FDA Memorandum of Understanding*, *supra* note 136.
[186] *Id.*

Attempts to codify cultivated-meat regulation into statute have begun. The formal agreement may be further solidified by legislation like the "Food Safety Modernization for Innovative Technologies Act."[187] In December 2019, Senators Mike Enzi of Wyoming and Jon Tester of Montana introduced the bill that formalizes the agreement between FDA and USDA to jointly regulate cell-based meat products.[188] The bill proposed a formal regulatory system to address cell-based meat by defining adulteration and misbranding specifically for food produced using animal cell culture technology.[189] The now dormant bill sought largely to codify the formal agreement, clarifying that FDA will oversee cell collection, proliferation, and culturing before oversight authority is transferred to USDA upon harvesting of the cells for further processing and packaging.[190] The relevant provisions in the bill would have also required FDA and the USDA to share information and collaborate.[191] It is likely that we will continue to see such provisions added into future bills.

Although the December 2019 bill largely mirrors the existing FDA–USDA agreement, there is a potential concern that solidifying the agreement into statute might tip the scales of certainty too far, locking in the existing agreement at the expense of regulatory flexibility.[192] Others are concerned that an inter-agency agreement is inferior to single-agency jurisdiction because of the risk of "gaps in regulations and misunderstandings."[193]

*(b) Planning for Implementation*

In order to determine how to regulate cell-based meat, the FDA and USDA formed working groups focused on cell-based meat and poultry production in the summer of 2019.[194] There are three

---

[187] Food Safety Modernization for Innovative Technologies Act, S. 3053, 116th Cong. (2019).

[188] *Id.*

[189] *Id.*

[190] *Id.*

[191] *Id.*

[192] *Ensuring a Safe Food Supply*, U.S. FOOD & DRUG ADMIN, 14, https://www.fda.gov/media/85938/download [https://perma.cc/D7QC-SE67].

[193] Simon M. Shane, Editorial, *Bill on Regulation of Cell-Cultured Technology. Effectively a Justification for a Comprehensive Federal Food Agency?*, CHICK-NEWS.COM (Jan. 2, 2020), http://www.chick-news.com/editorial.aspx [https://perma.cc/WYB9-3RXR].

[194] *USDA–FDA Memorandum of Understanding*, *supra* note 136.

working groups: (1) "premarket assessment" led by FDA, (2) "transfer of jurisdiction" which is focused on creating a seamless transition in oversight from FDA to USDA, and (3) "labeling" led by USDA.[195] The premarket assessment group has actively engaged with start-up companies to understand the various production methodologies and associated risks.[196] FDA and FSIS are also engaging with industry to help inform the details of how the agencies will ultimately regulate this sector. As of this writing, FSIS has indicated that it plans to develop new regulatory requirements for the labeling of cell-based meat and poultry products falling under its jurisdiction meat.[197] Currently, FDA is not expected to release new regulations with regard to premarket safety, inspection or labeling.[198]

At the same time that U.S. regulators are determining how to regulate (and name) cell-based meat, industry stakeholders will also need to reconcile U.S. regulations with state-based legislation, along with regulations applied in other countries. This will continue to be an evolving area where all interested parties are engaging in innovation, safety concerns, transparency in communication, and protection of identity of ethnically traditional products.

## II. FOOD SAFETY AND CELL-BASED MEAT

In this Part, we discuss the regulation of food safety for cell-based meat. In Section II.A, we describe the food-safety concerns surrounding cell-based meat generally. In Section II.B, we discuss the current tentative regulatory framework, which consists of an agreement between FDA and the USDA to jointly regulate the industry, but which lacks precise industry guidance on procedures to ensure regulatory compliance—guidance that is needed given some potential roadblocks in the current regulatory framework. Then, in Section III.C, we discuss some potential issues, including the role of tort liability, possible efforts by states to regulate

---

[195] *Id.*

[196] U.S. FOOD & DRUG ADMIN., PUBLIC MEETING: FOODS PRODUCED USING ANIMAL CELL CULTURE TECHNOLOGY, 16, 24 (2018).

[197] We learned this information by attending the FDLI Annual Conference in May 2019 and subsequent stakeholder meetings at USDA-FSIS in Fall 2019.

[198] *Id.*

cultivate meat food safety, and the role of regulatory environments outside the United States in the development of the industry.

### *A. Food Safety Concerns*

Overall food-safety concerns parallel two dominant theories of products liability in tort: design defects (i.e., inherent safety of foods and food ingredients from a biological perspective) and manufacturing defects (i.e., safety in the manufacturing process and subsequent handling steps). Or, put more simply, safety of the foods themselves and safety within the manufacturing and distribution process. Food safety risks within the manufacturing and distribution process can be further subdivided based on time: pre-harvest risks (or, for conventional meats, pre-slaughter) and post-harvest risks (or, post-slaughter).[199]

In the cultivated-meat context, pre-harvest risks arise at the steps of cell collection, cell banking, and early cell growth and differentiation.[200] Post-harvest risks include growing the product in a bioreactor, harvesting of the product from the bioreactor, and any downstream processing and handling.[201]

Many of the food safety concerns pertinent to conventionally produced meat also apply to cell-based meat.[202] For instance, either can be contaminated by certain foodborne pathogens, and can spoil.[203] And the post-bioreactor processing of cell-based meat will very closely resemble that of conventionally produced meat, as will many of the associated risks.[204]

Cell-based meat may also avoid some of the safety concerns of conventional food production. For instance, avoiding the raising and slaughter of herds of whole animals avoids the risk of pathogen

---

[199] U.S. FOOD & DRUG ADMIN., *supra* note 196 at 149.

[200] Elaine Watson, *So the FDA and USDA will share oversight for cell-based meat… but what will this mean in practice*, FOODNAVIGATOR USA (July 30, 2019, 10:10 AM), https://www.foodnavigator-usa.com/Article/2019/01/03/So-the-FDA-and-USDA-will-share-oversight-for-cell-based-meat-but-what-will-this-mean-in-practice [https://perma.cc/7XEN-ATQ5].

[201] Maribel Rios, *A Decade of Harvesting Methods*, BIOPROCESS INTERNATIONAL (June 1, 2012, 9:00 AM), https://bioprocessintl.com/downstream-processing/chromatography/a-decade-of-harvesting-methods-331186/ [https://perma.cc/NTQ7-7KYU].

[202] U.S. FOOD & DRUG ADMIN., *supra* note 196 at 115.

[203] *Id.* at 114, 116.

[204] *Id.* at 115.

contamination at those stages, as well as the hazards associated with animals catching disease (and the use of antibiotics, among other drugs that can otherwise enter the food supply).[205] The vast majority of contamination of conventionally produced meat occurs at slaughter, and around 90 percent of bacteria introduced into the food system by conventionally produced meat come from the skin or guts of animals.[206] In contrast, cell culture is done aseptically (i.e., in the absence of microbes), and modern laboratory analytical techniques make contamination relatively easy to detect in the controlled culture environments.[207]

But cell-based meat brings its own safety concerns too. For instance, cell-based meat may involve significantly more processing steps than conventional meat, with more accompanying opportunities for contamination.[208] Also, the fact that the cell cultures in cultivated-meat production undergo many more cell divisions than cells in an animal means that there is a higher risk of "genetic instability"—that is, the accumulation of genetic mutations that might give rise to cells with unwanted traits, such as cancer.[209] That said, cancer cells in meat are essentially harmless and cannot cause cancer in humans,[210] but there is the strong possibility that the public is unlikely to be comforted by this fact, and that regulators may not be either. In the biomedical context, the scientific community has developed ways to watch and control for genetic instability, which will need to be expanded into the cultivated-meat context.[211] Likewise, cell-based meat will involve the use of various cell types and chemical compounds not used in conventional meat processing—the risk of each will need to be accounted for. Industry would benefit from clear guidance on

---

[205] Consider that almost all ground beef probably has fecal bacteria in it. *See* Tom Philpott, *There Is Poop in Basically All Hamburger Meat*, MOTHERJONES (Aug. 24, 2015), https://www.motherjones.com/food/2015/08/poop-ground-beef-superbugs-antibiotic-resistant/ [https://perma.cc/YWY5-CBYE].

[206] Rebecca Voelker, *Cardiologist Trades Stem Cells for Cell-Based Meat*, 320 JAMA 1303, 1305 (2018).

[207] *See* Post & Hocquette, *supra* note 40, at 435 ("Other toxic conditions are equally unlikely to sustain survival and growth of cells in culture, so the cells serve as their own coal mine parakeets.").

[208] Eric Muraille, 'Cultured' meat could create more problems than it solves, THE CONVERSATION (Nov. 28, 2019 1:27 PM), https://theconversation.com/cultured-meat-could-create-more-problems-than-it-solves-127702 [https://perma.cc/646R-CVDS].

[209] *See* Post & Hocquette, *supra* note 40.

[210] *Id.*

[211] *Id.*

how the management of these risks in the cultivated-meat context will differ from the biomedical context.

### *B. Implications of Current FDA–USDA Cooperative Regulation Model*

Under current FDA and USDA policies, all human foods must be evaluated for biological, chemical, and physical risks.[212] Accordingly, USDA-regulated establishments are required to create and maintain a Hazard Analysis Critical Control Points (HACCP) plan, which USDA describes as a "logical, scientific system that can control safety problems in food production."[213] FDA-regulated establishments are required to create and maintain a Hazard Analysis and Risk-Based Preventive Controls ("HARPC") Plan.[214] These plans will be required for the establishments involved in cell-based meat.

A key pragmatic consequence of the FDA–USDA agreement is in the extent of premarket inspection. The FDA's inspection practices are guided by the Food Safety Modernization Act ("FSMA"), which mandates a risk-based approach to inspection frequency.[215] In contrast, USDA interprets its statutory mandate to mean that its inspectors must be at *every* regulated establishment during operating hours, regardless of risk.[216] All USDA-regulated establishments involved in cell-based meat-making would accordingly need to comply with USDA

---

[212] *See* 21 U.S.C. § 341 (2018).

[213] FOOD SAFETY & INSPECTION SERV., U.S. DEP'T AGRIC., GUIDEBOOK FOR THE PREPARATION OF HACCP PLANS, at C-1 (1997), http://haccpalliance.org/alliance/haccpmodels/guidebook.pdf [https://perma.cc/Z36Q-2MP4]; Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806 (July 25, 1996) (requiring that "all meat and poultry establishments develop and implement a system of preventive controls . . . known as HACCP").

[214] 21 C.F.R. §§ 117.126–117.190 (2019); CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE, HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD: GUIDANCE FOR INDUSTRY (2018) [https://perma.cc/NQ3Q-ZLC6].

[215] Brian P. Sylvester, *Clean Meat Staking Its Claim amid Regulatory Uncertainty*, FOOD SAFETY NEWS (July 1, 2018), https://www.foodsafetynews.com/2018/07/clean-meat-staking-its-claim-amid-regulatory-uncertainty/ [https://perma.cc/M7TK-K6QK].

[216] *Id.*

inspection,[217] storage,[218] sanitation,[219] and other regulatory requirements.[220] Thus, to the extent that a step of production is USDA-regulated, a higher burden will be imposed on producers.

Likewise, FDA will have to develop a regulatory approach for chemical components used in the manufacturing process.[221] Cellular agriculture involves the use of cell-culture media. The food additive petition pathway or GRAS Notice review process may be used by companies to establish the safety of cell-based meat inputs.[222]

Despite the willingness of FDA and the USDA to cooperatively regulate cell-based meat, there are potential roadblocks under the current regulatory scheme. For one, the current *formal* regulations in place are expressly directed to conventionally produced meat. And on the FDA front, current Agency guidance on cell line development and cell banking contemplates doing so in the biomedical space—not food production.[223] Accordingly, it is essential that USDA and FDA issue new guidance detailing exactly how cell-based meat fits within their existing statutory and regulatory frameworks.

### *C. The Way Forward: Other Potential Issues*

#### *1. Another Possible Regulation Lever: Tort*

The legal safety landscape in general includes both ex ante and ex post mechanisms.[224] Common ex ante mechanisms include regulations, inspections and labeling requirements.[225] Common ex post mechanisms include tort liability, equitable relief, mandatory

---

[217] *See* 21 U.S.C. § 606(a) (2018).

[218] *See id.* § 624.

[219] *See id.* § 608.

[220] *See* 9 CFR §§ 2.50-2.55 (2020).

[221] Sylvester, *supra* note 220.

[222] Sylvester, *supra* note 220.

[223] *See* CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CHARACTERIZATION AND QUALIFICATION OF CELL SUBSTRATES AND OTHER BIOLOGICAL MATERIALS USED IN THE PRODUCTION OF VIRAL VACCINES FOR INFECTIOUS DISEASE INDICATIONS 9 (2010), https://www.fda.gov/media/78428/download [https://perma.cc/AU2G-DVY3].

[224] David Rosenberg, *Response: Mandatory-litigation class action: the only option for mass tort cases*, 115 HARV. L. REV. 831, 833 (2002).

[225] *Id.* at 832.

recalls and seizures, and penalties.[226] Somewhere in the middle are informal enforcement mechanisms like warning letters or social media–based shaming.

Tort liability may be of biggest concern to cultivated-meat producers. [227] Tort liability at least plays a significant role in food safety; the potential for exposure to lawsuits continues to shape food-industry practices, both before and after the introduction of regulation. [228] Although tort is primarily concerned with compensation and redress, it also serves a quasi-regulatory function to the extent that it provides incentives for particular behaviors and penalizes straying from particular standards of care.[229] An active tort system may also impede innovation in an area of technology,[230] although it might also spur innovation (for instance, innovation in safety-related science or technology).

Why a fear of torts for cell-based meat? The technology is not well-understood by the public, and it is scientifically complex.[231] As with any scientifically complex product, it is likely to rouse consumer suspicion[232] and potentially attract lawsuits, as

---

[226] *Id.*

[227] *See generally* Philip Chen, ENSURING SAFE FOODS AND MEDICAL PRODUCTS THROUGH STRONGER REGULATORY SYSTEMS ABROAD 253, 255 (Jim E. Riviere & Gillian J. Buckley eds., 2012), https://www.ncbi.nlm.nih.gov/books/NBK201154/ [https://perma.cc/3AK3-L997].

[228] *Id.*

[229] *See id.* at 256–57.

[230] Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 286 (2008) (contending that "courts' reliance on customs and conventional technologies as the benchmark for assigning tort liability chills innovation and distorts its path" and "subsidizes users and replicators of conventional technologies").

[231] *E.g.*, Peter H. Feindt & P. P. Marijin Poortvliet, *Consumer Reactions to Unfamiliar Technologies: Mental and Social Formation of Perceptions and Attitudes Toward Nano and GM Products*, J. RISK RESEARCH (Mar. 25, 2019), https://www.tandfonline.com/doi/pdf/10.1080/13669877.2019.1591487 [https://perma.cc/8LG2-NXB3] ("Limited understanding of the technological principles and lack of (visible) products prevent the formation of experience-based attitudes and behavioral intentions.")

[232] *E.g.*, *id.* at 7; *Cf.* Shantel Nubia, *Did You Know There Is Cancer in Your "Impossible Burger"?!*, NUORIGINS (Nov. 18, 2019), https://www.nuorigins.com/did-you-know-there-is-cancer-in-your-impossible-burger/ [https://perma.cc/39DE-EZV4]. (suggesting sources such as this conflate scientific issues, which means juries can too). *See, e.g.*, Michael Hiltzik, Column, *Did a Jury Ignore Science When It Hit Monsanto with a $2-Billion Verdict?*, LA Times (May 17, 2019, 6:20 AM), https://www.latimes.com/business/hiltzik/la-fi-hiltzik-monsanto-glyphosate-verdict-20190517-story.html [https://perma.cc/2LMZ-RR2K].

has been the case with plant-based meat substitutes.[233] Consider the analogous context of plant-based meat. There, some consumers allege that the products in question contain "cancer."[234] Really, they mean *glyphosate*, an extremely well-characterized pesticide that acts on a biological target not contained in humans.[235] Even vanishingly small levels of controversial chemicals—the supposedly tested level of glyphosate detected was 11.3 parts per billion, which is 1000 times lower than California's Prop 65 limit or the EPA's limit in dried pea and soybean[236]—might be enough to spark outcry or litigation.

The above underscores the essentiality of FDA and USDA providing thorough, scientifically grounded guidance on demonstrating safety of cultivated-meat products, as well as constituents used during their manufacture.

### *2. Preemption Issues and Potential State-Law Pushback*

Preemption originates from the Supremacy Clause and provides that state law must yield to federal law.[237] As a doctrine it is divided into express or implied preemption, and implied preemption is further divided into field and conflict preemption.[238]

Under field preemption, a scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."[239] Under conflict

---

[233] *See, e.g.*, Kim Bellware, *Vegan Sues Burger King, Claiming Meatless Impossible Whopper Is 'Contaminated' by Beef Fat*, WASH. POST (Nov. 19, 2019, 11:01 AM), https://www.washingtonpost.com/food/2019/11/19/vegan-sues-burger-king-claiming-meatless-impossible-whopper-is-contaminated-by-beef-fat/ [https://perma.cc/U7J6-MUWQ].

[234] *E.g.*, Nubia, *supra* note 240; Evan Anderson, *Lies About Roundup in the Impossible Burger*, REASONED VEGAN (July 24, 2019), https://thereasonedvegan.com/2019/07/24/lies-about-roundup-in-the-impossible-burger/ [https://perma.cc/T3UY-A5U9] (noting that the group Moms Across America characterized the Impossible Burger as "*soaked* in glyphosate").

[235] *See generally Questions and Answers on Glyphosate*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/pesticides/questions-and-answers-glyphosate [https://perma.cc/D488-L42T].

[236] Anderson, *supra* note 242.

[237] *See* Virginia Uranium, Inc. v. Warren, 139 S. Ct. 1894, 1901 (2019); U.S. CONST. art. IV, cl. 2.

[238] *Virginia Uranium*, 139 S. Ct. at 1901.

[239] Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) (internal quotation omitted).

preemption, a state law is invalid because it "stands as an impermissible 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"[240] Federal regulation is a frequent source of preemption—for instance, courts have often pointed to the presence of federal regulation to preempt consumer lawsuits.[241] As the Court has noted, Congressional intent is "the ultimate touchstone."[242]

The Supreme Court has cautioned, however, that "[i]nvoking some brooding federal interest or appealing to a judicial policy preference should never be enough to win preemption of a state law; a litigant must point specifically to 'a constitutional text or a federal statute' that does the displacing or conflicts with state law.'"[243] The federal bench appears to be increasingly wary of implied preemption claims,[244] concerned over "serious intrusion[s] into state sovereignty."[245]

To the extent that a federal law does not displace or conflict with it, then, a state might aim to pass a law that directly or indirectly regulates safety issues concerning cell-based meat. Such a law in a particularly influential state such as California might affect a substantial portion of the cultivated-meat market. For instance, a state might seek to impose additional safety requirements or inspection standards for the cultivated-meat industry, might provide for increased damages for tort plaintiffs in related cases, might create new causes of action for prospective cultivated-meat consumers, or might impose particular taxes or registration requirements.

---

[240] Virginia Uranium, 139 S. Ct. at 1907 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

[241] William Buzbee et al., *The Truth About Torts: Rethinking Regulatory Preemption and Its Impact on Public Health,* 902 CTR. FOR PROGRESSIVE REFORM 4 (2009) https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1115&context=other [https://perma.cc/WC3B-GLXB].

[242] Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485, 116 S. Ct. 2240 (1996) (internal quotation marks omitted).

[243] *Virginia Uranium*, 139 S. Ct. at 1901 (quoting Puerto Rico Dep't of Consumer Affairs v. ISLA Petroleum Corp., 485 U.S. 495, 503 (1988)).

[244] *See also* Altria Grp., Inc. v. Good, 555 U.S. 70, 77 (2008) ("[W]hen the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors preemption.")(quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

[245] *Virginia Uranium*, 139 S. Ct. at 1904–05 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 488 (1996) (plurality opinion)).

A handful of federal statutes are most relevant to preemption challenges to state food-safety laws that might affect cell-based meat. First, the Food Safety Modernization Act of 2011 ("FSMA"), which amended the FDCA and gave FDA new regulatory authority regarding food safety.[246] Second, the USDA-empowering Federal Meat Inspection Act of 1906 ("FMIA"), which criminalized adulteration of meat and ensured sanitary meat production conditions.[247] Third, the Poultry Products Inspection Act of 1957 ("PPIA"), which enabled USDA inspection of domesticated birds slaughtered and processed into food.[248] All three contain preemption provisions that have been interpreted in case law.[249]

The FMIA's express preemption provision prevents states from imposing upon USDA-regulated meat facilities any requirements within the scope of the FMIA and are "in addition to, or different than those made under" the FMIA.[250] In *National Meat Association v. Harris*, the Supreme Court held that this provision prevented California from applying against federally inspected swine slaughterhouses a California criminal law prohibited sale of meat from "nonambulatory" animals.[251] Indeed, the Court held that even "non-conflicting" requirements were preempted.[252] California had enacted the statute after public outcry after undercover video of slaughterhouse operations surfaced.[253] This broad interpretation of the FMIA's preemption provision might

---

[246] FDA Food Safety Modernization Act, Pub. L. No. 111–353, 124 Stat. 3885 (2011) (codified in 21 U.S.C. § 301 (2018)).

[247] Federal Meat Inspection Act of 1906, Pub. L. No. 59–252, 33 Stat. 1256 (codified as amended at 21 U.S.C. § 601 (2018)).

[248] Poultry Products Inspection Act of 1957, Pub. L. No. 85–172, 71 Stat. 441 (codified as amended at 21 U.S.C. § 451 (2018)).

[249] FDA Food Safety Modernization Act, Pub. L. No. 111–353, 124 Stat. 3885 (2011) (codified in 21 U.S.C. § 301 (2018)); Federal Meat Inspection Act of 1906, Pub. L. No. 59–252, 33 Stat. 1256 (codified as amended at 21 U.S.C. § 601 (2018)); Poultry Products Inspection Act of 1957, Pub. L. No. 85–172, 71 Stat. 441 (codified as amended at 21 U.S.C. § 451 (2018)).

[250] 21 U.S.C. § 678 (2018); *see also Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 458 (2012); 9 C.F.R. § 301.2 (2019) (defining for purpose of inspections "official establishment" as "[a]ny slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations of this subchapter.").

[251] Nat'l Meat Ass'n, 565 U.S. at 459–60 ("The clause prevents a State from imposing any additional or different—even if non-conflicting—requirements that fall within the scope of the Act and concern a slaughterhouse's facilities or operations.").

[252] *Id.* at 459–60.

[253] *Id.* at 458.

shield cell-based meat from state regulation. To the extent that cultivated-meat companies operate outside the realm of the FMIA, however (e.g., cell-cultured seafood or wild game), they may still be at risk.[254]

The PPIA contains a similar preemption provision prohibiting states from imposing "ingredient requirements" that are "in addition to, or different than" the federal law and its accompanying regulations.[255] In *Association des Éleveurs v. Becerra*, California imposed a law requiring that foie gras only be made from the livers of birds that were not force-fed.[256] Although producers of foie gras challenging the law argued that this constituted an "ingredient requirement," the Ninth Circuit found no preemption, in light of the ordinary meaning of "ingredient" and the "plain language and purpose" of the PPIA.[257] The court held that "ingredient requirements" were limited to "physical components of a poultry product."[258] This interpretation of the PPIA's preemption provision, to "the physical components [and] not the way the animals are raised," suggests that states may have room to legislate based on the production method of a cell-based meat product.[259]

As for the FSMA, it contains two *non-preemption* clauses.[260] One occurs specifically in the context of Hazard Analysis and Risk-Based Preventive Controls requirements, and reads:

> Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production of food. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.[261]

---

[254] *See, e.g.*, People v. Santorsola, 170 Cal. Rptr. 3d 819, 823–24 (Cal. Ct. App. 2014) (holding that FMIA preemption did not apply where defendant charged with animal held auction at establishment not subject to inspection under the FMIA).

[255] 21 U.S.C. § 467e (2018).

[256] Ass'n des Éleveurs de Canards et D'Oies du Québec v. Becerra, 870 F.3d 1140 (9th Cir. 2017).

[257] *Id.* at 1146.

[258] *Id.* at 1147.

[259] *Id.* at 1147–48.

[260] 21 U.S.C. § 350g(l)(6) (showing a hazard analysis and risk-based preventive controls); 21 U.S.C. § 350h(f)(5) (showing produce controls).

[261] 21 U.S.C. § 350g(l)(6).

In contrast to USDA regulation, which may shield producers from tort litigation and additional state requirements, then, FDA—while allowing a perhaps more flexible inspection regimen—does not provide the same defensive preemption.[262]

Preemption is a nuanced, case-by-case subject, and full exploration of the extent of preemption here is beyond the scope of this paper. But the cultivated-meat industry will likely need to keep the prospect of state legislation in mind in developing its strategy. Similarly, legislators, FDA, and the USDA might keep such possibilities in mind when developing new guidance, regulations, or legislation.

### 3. *Learning from Past Experiences: Cloned Meat and Bioengineered Meat*

Regulators and industry might do well to look to previous examples of innovative meat technologies for guidance: cloned meat and bioengineered meat.

#### *(a) Cloned Meat*

*Cloned meat* is derived from cloned animals or their offspring.[263] The late 1990s saw a flurry of commercial interest in cloning, with a prominent example being Dolly the Sheep's debut in 1996.[264] Cloning offered the promise of being able to near-perfectly replicate animals with particularly desirable characteristics.[265] The food-industry potential was obvious.[266]

---

[262] *See also Food Safety Modernization Act / Effect on States*, NAT'L CONF. ST. LEGISLATURES (Mar. 24, 2014), https://www.ncsl.org/research/agriculture-and-rural-development/food-safety-modernization-act.aspx [https://perma.cc/PYU3-AB3G] ("The act primarily addresses regulatory gaps at the FDA and does not place a burden on the states. States are not required to perform any of its provisions nor does the law super cede state law. Food producers and processors will still have to follow state rules, in addition to the new FDA requirements.").

[263] *See* Marlowe Hood & Pascale Mollard, *The Dolly legacy: Are you eating cloned meat?*, PHYS.ORG (July 4, 2016), https://phys.org/news/2016-07-dolly-legacy-cloned-meat.html [https://perma.cc/5RUY-VBZS].

[264] *See generally* Karen Weintraub, *20 Years After Dolly the Sheet Led the Way—Where Is Cloning Now?*, SCI. AM. (July 5, 2016), https://www.scientificamerican.com/article/20-years-after-dolly-the-sheep-led-the-way-where-is-cloning-now/ [https://perma.cc/U5VP-7D39] (suggesting that Doll was the first cloned mammal).

[265] *Id.*

[266] Hood and Pascale, *supra* note 271.

Seeing both increased interest and increased outcry, FDA requested in 2001 that food producers not introduce any cloned meat onto the market until an extensive safety review could be completed.[267] The agency conducted a multi-year investigation of safety risks inherent in cloned meat.[268] More specifically, the agency looked at whether there were any scientific differences between meat products from cloned and non-cloned animals (in addition to differences in the animals themselves).[269] Finding no inherent safety concerns after years of exhaustive study, FDA in 2008 lifted its voluntary moratorium and released three documents: a lengthy 968-page risk assessment,[270] a risk management plan,[271] and guidance for industry.[272] The USDA did not lift a parallel voluntary moratorium that it has imposed.[273]

The safety evaluation for cloned meat specifically excluded genetically modified animals.[274] The analysis was also limited to cattle, swine, and goats.[275] FDA pointed to the long history of use of the source animals generally for food and pointed out that cloned meat wasn't without risks, but those risks were essentially identical to conventionally produced meat.[276] The agency found

---

[267] *Animal Cloning*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/safety-health/animal-cloning [https://perma.cc/9EEX-K5M2]

[268] *Id.*

[269] *Risk Management Plan*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/animal-cloning/risk-management-plan [https://perma.cc/P4SA-9NSZ] ("Blood values, enzymes, overall health, and behavioral observations for those clones are all in same ranges seen in conventionally bred animals of the same breed and raised on the same farms. In addition, meat and milk from clones do not appear to differ significantly in composition from meat and milk from conventionally bred animals.") [hereinafter *Risk Management Plan*].

[270] CTR. FOR VETERINARY MED. ET AL., ANIMAL CLONING: A RISK ASSESSMENT (2008), https://www.fda.gov/files/animal%20&%20veterinary/published/Animal-Cloning--A-Risk-Assessment.pdf [https://perma.cc/UUQ8-4HL3] [hereinafter CLONING RISK ASSESSMENT].

[271] *Risk Management Plan*, supra note 269.

[272] U.S. DEP'T OF HEALTH & HUMAN SERV. ET AL., GUIDANCE FOR INDUSTRY: USE OF ANIMAL CLONES AND CLONE PROGENY FOR HUMAN FOOD AND ANIMAL FEED (2008) [hereinafter CLONING GUIDANCE].

[273] Christopher Doering, *No Quick End for Cloning Product Moratorium: USDA*, REUTERS (Apr. 7, 2008, 1:31 PM), https://in.reuters.com/article/us-cloning-food-usda/no-quick-end-for-cloning-product-moratorium-usda-idINN0438308520080407 [https://perma.cc/B7FM-AB38].

[274] *Risk Management Plan*, *supra* note 277.

[275] *Id.*

[276] *Id.* (indicating that "epigenetic dysregulation, the inappropriate expression of genes, including over- or under-expression, or expression at the wrong time" can occur whether or not the animal is cloned).

that the reviewed cloned livestock "meet all of the developmental milestones appropriate for their species, and become otherwise indistinguishable from sexually-reproduced comparators."[277] Given all this, the agency concluded that cloned meat would be regulated under the same constraints as conventionally produced meat.[278] In its guidance for industry, FDA announced:

> [T]he agency believes that food products from progeny of a clone from any species currently consumed as food are suitable to enter the food and feed supply under the same controls as applied to any animal that is the product of sexual reproduction. FDA does not have recommendations for any additional measures related to the use of the progeny of clones for the production of food for humans or feed for animals based on the fact that these are progeny of clones.[279]

The cloned-meat regulatory model—a multi-year moratorium pending a conclusion that the technology as a whole produces meat just like any other—is not ideal for cell-based meat. For one, clones are by definition nearly identical to the animals from which they are derived.[280] But a strength of cell-based meat is the ability to very finely tweak a product and imbue it with particular characteristics—to be different.[281] That said, other cell-based meat seeks to mimic conventionally produced meat as closely as possible. Thus, one could argue that there is no one-size-fits-all scientific question that a multi-year exhaustive study could address. Necessary risk questions will likely be product-to-product, as new genes and new ingredients themselves will need to be considered, as well as new manufacturing methods.

---

[277] *Id.*

[278] *Id.*

[279] See CLONING GUIDANCE, *supra* note 280, at 3.

[280] D.N. Wells, *Animal cloning: problems and prospects,* 24 REV. SCI. TECH. OFF. INT. EPIZ. 251, 251 (2005).

[281] Tom Ireland, *The artificial meat factory – the science of your synthetic supper*, SCIENCE FOCUS (May 23, 2019), https://www.sciencefocus.com/future-technology/the-artificial-meat-factory-the-science-of-your-synthetic-supper/ [https://perma.cc/VCF8-C2XK].

Additionally, cloned animals were only expected to be a minor portion of what continued to be a conventional meat industry.[282] Clones were expected mostly to serve as breeding stock.[283] Thus, a temporary moratorium had little disruption on the industry as a whole. In contrast, cell-based meat producers seek to establish a production pathway outside conventional meat, lacking some elements (like slaughter) and adding others (like cell banks and tissue bioengineering facilities). A moratorium on cell-based meat would be a moratorium on that industry as a whole.

The cloned-meat approach would also stifle innovation. FDA imposed what was essentially a moratorium from 2001 to 2008.[284] A similar approach here would undoubtedly deter investment in research and development and would stifle the pace of current companies, most of which are in early and rapid phases of investment and seek to get a product on the market in the next few years.[285] It would also advantage large corporations with other product lines and the ability to keep cell-based meat on hold for years; in contrast, smaller companies aimed only at cultivated-meat development would find themselves without a revenue source in the near future.

Still, several lessons from cloned meat do translate over to the cell-based meat context. First, FDA looked at some of the products *themselves* (e.g., cloned milk, which was within the ambit of the risk assessment) for comparative safety assessments,[286] rather than merely their origins.[287] Additionally, FDA drew heavily from peer-reviewed research in the scientific community.[288] And FDA sought to include cloned meat within its

---

[282] *Risk Management Plan*, *supra* note 277 (suggesting the impact of cloning in scientific research and development exceeds its impact in agriculture).

[283] *Id.*

[284] *Id.* (suggesting FDA requests for voluntary changes are common informal enforcement mechanisms); *see* Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 90 (2014).

[285] *See e.g.,* Amelia Lucas, *Lab-grown meat start-up raises $14 million to build production plant*, CNBC (Oct. 10, 2019, 8:00 AM), https://www.cnbc.com/2019/10/10/future-meat-technologies-a-lab-grown-meat-start-up-raises-14-million-dollars.html [https://perma.cc/B25G-5N7M].

[286] *See also, e.g.*, CLONING RISK ASSESSMENT, *supra* note 278, at 7 (stating that comparison included "measurements of gross composition (e.g., carcass composition, percent fat and protein) as well as detailed analyses of vitamins and minerals, fatty acid profiles, and protein characterization of meat and milk produced by clones").

[287] *See generally* Norton, *supra* note 29, at 170.

[288] CLONING RISK ASSESSMENT, *supra* note 278, at ii.

existing regulatory safety framework. Finally, FDA's safety-assessment approach is probabilistic and pragmatic, looking not only at possible risks but the likelihood of their occurrence.[289] For instance, FDA announced an intent to allow cloned meat into the market despite gaps in its data (for instance, data on animals besides cattle, swine, and goats, and some incomplete data even for these).[290] This philosophy allows for greater flexibility in innovation than competing philosophies (such as the precautionary principle, which tends to suppress introduction of new technologies until affirmatively proven safe).[291] These aspects will likely be useful in the cultivated-meat context, as there is a growing scientific community available for expert consultation as well as abundance abilities to compare products analytically for composition and safety.[292]

*(b)* Bioengineered Foods

What of *bioengineered food*, then? First, some terminology: Under 7 U.S.C. § 1639(1), "bioengineering," with respect to food, refers to food having genetic material that has been modified through in vitro recombinant DNA techniques and which modification could not have been obtained without those techniques.[293] The term "bioengineered," at least as used in the U.S. regulatory space, is similar to "genetically modified," "genetically engineered," or "genome edited"—but not quite the same. [294] There are some differences in each of the above categories, but collectively they

---

[289] *See* CLONING RISK ASSESSMENT, *supra* note 278, at 425–30.

[290] Animal Cloning and Food Safety, FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/animal-cloning-and-food-safety [https://perma.cc/4CA4-L3L4].

[291] *See* Sci. Commc'n Unit, Eur. Comm'n, *Future Brief: The Precautionary Principle, Decision-Making Under Uncertainty*, SCI. FOR ENVT'L POL'Y, Sept. 2017, at 3, 7–8; Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 PENN L. REV. 1003 (2003); Petetin, *infra* note 338, at 172 ("An 'overreaction' resulting in a strict application of the [precautionary] principle could produce detrimental effects as it would stop the development of the technology, and could result in a moratorium, creating its own set of counterproductive consequences, i.e. preventing the expansion of an innovation which could provide a solution to world hunger and food security.").

[292] *See generally* CLONING RISK ASSESSMENT, *supra* note 278, at i-iii.

[293] 7 C.F.R. § 66.1 (2019).

[294] *Id.*

refer to organisms in which at least some DNA has been changed from its natural state. [295]

Tinkering with plant genetics is a time-honored tradition,[296] and traditional breeding methods have largely escaped regulation.[297] But with the rapid evolution of molecular biology in the 1980s and 1990s (which, being particularly scientific, arguably frightened consumers), FDA took notice and in 1992 published a policy—the Plant Biotechnology Consultation Program—asking that developers of new bioengineered foods voluntarily consult with FDA during their development.[298] Such consultation comes in three forms: "biotechnology final consultations, new protein consultations, and rarely, establishment of a food master file or submission of a food additive petition."[299] That said, FDA insists: "We regulate human and animal food from genetically engineered ("GE") plants like we regulate all food."[300]

Under FDA's guidance, developers are encouraged first to undergo initial consultations with the agency to "facilitate resolution of safety, nutritional, and regulatory issues."[301] Eventually, when a firm believes that it has enough data to show

---

[295] *Id.*

[296] *See* Richard Molinar, *Traditional Plant Breeding vs. Genetic Engineering – A Primer*, FARMPROGRESS (Oct. 26, 2012), https://www.farmprogress.com/management/traditional-plant-breeding-vs-genetic-engineering-primer [https://perma.cc/9TSZ-37W8].

[297] *See* Andrew Pollack, *By 'Editing' Plant Genes, Companies Avoid Regulation*, N.Y. TIMES (Jan. 1, 2015), https://www.nytimes.com/2015/01/02/business/energy-environment/a-gray-area-in-regulation-of-genetically-modified-crops.html[https://perma.cc/4R5C-48XN]; *see* also NAT'L RES. COUNCIL & INST. OF MEDICINE, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 27 (National Academies Press, 2004) ("Induced-mutation crops in most countries (including the United States) are not regulated for food or environmental safety.").

[298] *Submissions on Bioengineered New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-new-plant-varieties/submissions-bioengineered-new-plant-varieties [https://perma.cc/868K-AQQT].

[299] *Id.*

[300] *How FDA Regulates Food from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-new-plant-varieties/how-fda-regulates-food-genetically-engineered-plant [https://perma.cc/A5EA-U8V4].

[301] *Consultation Procedures under FDA's 1992 Statement of Policy for Foods Derived from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/consultation-procedures-under-fdas-1992-statement-policy-foods-derived-new-plant-varieties [https://perma.cc/N9P8-23KR] [hereinafter *New Plant Consultation Procedures*].

that a product is safe and FDCA-compliant, it undergoes a final consultation in which it submits to FDA a summary of its safety and nutritional assessments and meets with FDA scientists, if necessary, to clarify any remaining issues.[302] The process is overseen by the Biotechnology Evaluation Team ("BET")—comprising a consumer safety officer, a molecular biologist, a chemist, and environmental scientist, a toxicologist, and a nutritionist, with additional personnel if needed on a case-by-case basis.[303]

The safety assessment focuses on what is different about the new product and whether any "new material" in food made from a genetically engineered plant is safe when eaten.[304] Part of this comparison constitutes a nutritional and compositional comparison of the food with other foods from "traditionally bred plants or other comparable foods"[305] and inquires into the presence of possible new toxins or allergens.[306] As articulated in FDA's guidance, this is consistent with the concept of "substantial equivalence" of new foods.[307]

At the end of the consultation process, and after the BET makes its recommendation, FDA then makes publicly available details of the crop that was modified, the new or altered trait encoded by the genes that were changed, and various other details.[308]

Since 2006, FDA has also provided for an "early food safety evaluation" for "new non-pesticidal proteins produced by new plant

---

[302] *Id.*

[303] *Id.*

[304] *Consumer Info About Food from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-new-plant-varieties/consumer-info-about-food-genetically-engineered-plants [https://perma.cc/2ZQA-TT8N].

[305] *Id.*

[306] *How FDA Regulates Food from Genetically Engineered Plants*, *supra* note 308.

[307] *Statement of Policy-Foods Derived from New Plan 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/U5QN-C8BM].

[308] *See Final Biotechnology Consultations*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/submissions-bioengineered-new-plant-varieties/final-biotechnology-consultations [https://perma.cc/46RG-685R]; *Consultations on Food from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon [https://perma.cc/9YZT-75A4] [hereinafter *Database*].

varieties that are intended as food."[309] This evaluation does not operate as a supplement to the overall consultation as to the food itself.[310] As with those consultations, details of FDA consultations are provided to the public.[311] The purpose of the evaluation is public health–oriented, as FDA has expressed concern that field testing of genetically engineered plants may result in the low-level presence of new proteins from these plants in the food supply.[312] Interestingly, FDA's opinion is that proteins from genetically engineered plants will be "the same or quite similar to proteins commonly found in food."[313] Accordingly, FDA's focus is limited to "the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible people or could be a toxin in people or animals."[314]

Regulation of bioengineered food resembles regulation of new drugs in that developers are tasked with affirmatively demonstrating safety and submitting information to FDA on a case-by-case basis.[315] Unlike new-drug regulation, the program offers no product market exclusivity.[316] Further, the program is voluntary, and developers remain "legally obligated to ensure the safety of the food products they bring to market."[317] Thus, despite an expectation that developers conduct safety assessments and prove nutritional content, they likely lack any sort of preemption-based defenses to safety tort liability that drugs and medical devices, in contrast, may benefit from.

The bioengineered-food approach is not entirely an ideal model for cell-based meat. The approach, taken generally, assumes that the resulting foods are, like foods from cloned animals,

---

[309] *Submissions on Bioengineered New Plant Varieties*, *supra* note 306; *see also* Guidance for Industry; Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability, 71 Fed. Reg. 35688 (June 21, 2006) [hereinafter New Protein Guidance].

[310] *Submissions on Bioengineered New Plant Varieties*, *supra* note 306.

[311] *New Protein Consultations*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/submissions-bioengineered-new-plant-varieties/new-protein-consultations [https://perma.cc/T68K-4C79].

[312] New Protein Guidance, *supra* note 317.

[313] *Id.*

[314] *Id.*

[315] How GMOs are Regulated for Food and Plant Safety in the United States, U.S. FOOD & DRUG ADMIN. https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-food-and-plant-safety-united-states [https://perma.cc/T7DH-2RJG].

[316] See *id.*

[317] *How FDA Regulates Food from Genetically Engineered Plants*, *supra* note 308.

essentially the same foods. Aside from any genetic modification steps, production of the foods themselves is parallel to conventional foods.[318] This conclusion results from the fact that genetically engineered plants are typically almost indistinguishable from the original plants, and so it is enough to examine only differences in order to interrogate safety. Not so with cell-based meat. Some cell-based meat might be totally unlike anything in nature, but some is intended to be almost a cell-for-cell equivalent of conventionally harvested meat.[319] Still, cell-based meat is made from an entirely different route, even if the end product is indistinguishable. [320] Accordingly, a different analytical approach will likely be needed: for instance, perhaps a comprehensive biochemical and nutrition-based comparison to existing products; or a set of nutrition standards and safety benchmarks. Even if the analytical approach may need to differ, however, the concept of "substantial equivalence" may be a useful regulatory lodestar.[321]

Nonetheless, regulation of cell-based meat could draw in part from the bioengineered-food approach. For instance, a premarket consultation process with published criteria for evaluation would help ensure certainty and increase investor and innovator confidence in the pathway for new technologies.[322] Likewise, while such a process would probably not shield companies from tort liability on food-safety issues, it could serve as relevant evidence in any related litigation. Such a process might also help to lend confidence to consumers as to the safety of cell-based meat. But maybe that is optimistic: despite twenty years of publishing of consultations for genetically engineered plants, despite the publicity efforts of various governments,[323] despite the overwhelming presence of genetically engineered plants in the US

---

[318] *See, supra* note 275.

[319] *Mitosis/Cell Division*, supra note 36.

[320] Brown, *supra* note 30.

[321] *See, e.g.*, Schneider, *supra* note 33, at 1006–07 (discussing the doctrine of substantial equivalence). *But see id.* at 1015 (arguing that the doctrine should not apply to cell-based meat because even if cell-based meat will "replicate vascularization and fat content, among other requirements, to re-create the taste and texture of natural meat," doing so will "require crafting artificial equivalents").

[322] Watson, *supra* note 203.

[323] *E.g.*, Petetin, *infra* note 338, at 176 ("[F]or decades now, the EU institutions have been trying to convince EU citizens that GMOs and the resulting foods are safe but they have been largely unsuccessful.").

market (e.g., 89 percent of cotton and 94 percent of soybeans),[324] and despite overwhelming scientific consensus as to the general safety of genetically modified crops,[325] consumers still by-and-large view genetically modified food as fundamentally unsafe.[326]

### *4. Regulatory Receptivity Overseas*

The United States might look to other countries' approaches, as the first cultivated-meat launches may be overseas where regulatory pathways are clearer. For instance, JUST purportedly has a product ready—cell-based chicken nuggets—but is yet to decide on the proper country for launch, currently investigating the most favorable regulatory environment.[327] Later announcements narrowed the launch to Asia.[328]

In the EU, any "novel food" is regulated under a set of policy documents and regulations guided by the precautionary principle.[329] The European Commission has recently stated that cell-based meat falls within the ambit of the Novel Food Regulation, which provides for the safety and labeling evaluation by the European Food Safety Authority ("EFSA") for "food consisting of, isolated from, or produced from a cell culture or tissue culture from animals, plants, micro-organisms, fungi or algae."[330] The regulation requires pre-market authorization of

---

[324] *Recent Trends in GE Adoption*, U.S. DEP'T AGRIC., https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx [https://perma.cc/6GHC-GGMU].

[325] Jane E. Brody, *Are G.M.O. Foods Safe?*, N.Y. TIMES (Apr. 23, 2018), https://www.nytimes.com/2018/04/23/well/eat/are-gmo-foods-safe.html ("90 percent of scientists believe G.M.O.s are safe — a view endorsed by the American Medical Association, the National Academy of Sciences, the American Association for the Advancement of Science and the World Health Organization . . . .") [https://perma.cc/MM95-KESL].

[326] *Id.* (suggesting about one-third of consumers view genetically modified foods to be safe).

[327] *Cell Based Tech Weekly Nov. 2, 2019, supra* note 115; Nicole Axworthy, *JUST's $50 Slaughter-Free Chicken Nuggets Are Ready for Market*, VEGNEWS (Oct. 25, 2019), https://vegnews.com/2019/10/justs-50-slaughter-free-chicken-nuggets-are-ready-for-market [https://perma.cc/9V2X-6MLP].

[328] Catherine Lamb, *Cultured Meat Will Likely Debut in Asia, Not Silicon Valley. Here's Why.*, THE SPOON (Mar. 19, 2019), https://thespoon.tech/cultured-meat-will-likely-debut-in-asia-not-silicon-valley-heres-why/ [https://perma.cc/6RE4-THR3].

[329] *See generally* Petetin, *infra* note 338, at 177–79.

[330] *Answer Given by Mr. Andriukaitis on Behalf of the European Commission*, EUR. PARLIAMENT (Oct. 8, 2018), http://www.europarl.europa.eu/doceo/document/E-8-2018-004200-ASW_EN.html [https://perma.cc/D488-L42T]; *see also* Elaine Watson, *The 'World Is Watching' the Cell-Based Meat Industry, Says Memphis Meats VP: 'Subpar Early Products*

novel foods, including a safety assessment by the EFSA.[331] Depending on the details of how the EU regulates cell-based meat, it may benefit from a "substantial equivalence" pathway imposing a lower regulatory burden.[332] The regulation also provides for the imposition of post-market monitoring requirements for these foods if the Commission thinks that doing so is important for safety reasons.[333] Thus, although the hill may be steep in the EU, a pathway does exist. That said, the Novel Foods Regulation was drafted before the onset of cell-based meat, and, like with FDA and USDA, some new guidance may be required by regulators in the EU to adapt it to the cultivated-meat context.[334]

Similarly, comparatively clear pathways to market exist in Japan, Hong Kong, and Singapore.[335] In the relatively free-market regulatory environment of Hong Kong, food is much more flexibly regulated than in the United States.[336]

Ultimately, if the United States does not provide a clear enough pathway forward, other countries might lead the way. Even more drastically, the United States might consider simply consolidating food-safety regulation into one agency, as suggested, for instance, by some members of Congress.[337]

---

*Can Stigmatize an Entire Category for Decades to Come*,*'* FOOD NAVIGATOR-USA.COM (Feb. 11, 2019, 4:30 PM), https://www.foodnavigator-usa.com/Article/2019/02/11/The-world-is-watching-the-cell-based-meat-industry-says-Memphis-Meats-VP-Subpar-early-products-can-stigmatize-an-entire-category-for-decades-to-come_[https://perma.cc/YLE3-SHV6]; *See generally* Ludivine Petetin, *Frankenburgers, Risks and Approval*, 5 EUR. J. RISK REG. 168 (2014) (discussing regulation of cell-based meat in the EU).

[331] *Answer Given by Mr. Andriukaitis on Behalf of the European Commission*, *supra* note 338; Petetin, *supra* note 338, at 179–80.

[332] *See* Petetin, *supra* note 338, at 180.

[333] *Answer Given by Mr. Andriukaitis on Behalf of the European Commission*, *supra* note 338.

[334] Petetin, *supra* note 338, at 179.

[335] Watson, *supra* note 338; Deena Shanker, *These $50 Chicken Nuggets Were Grown in a Lab*, BLOOMBERG (Oct. 22, 2019, 6:35 AM), https://www.bloomberg.com/news/articles/2019-10-22/clean-meat-just-chicken-nuggets-grown-in-a-lab-coming-soon [https://perma.cc/VA83-QGM6].

[336] Lamb, *supra* note 336.

[337] Shane, *supra* note 196; Coral Beach, *Bill for Safe Food Act Seeks to Consolidate Federal Oversight*, FOOD SAFETY NEWS (June 27, 2019), https://www.foodsafetynews.com/2019/06/bill-for-safe-food-act-seeks-to-consolidate-federal-oversight/ [https://perma.cc/KNL3-GEPU].

## III. PRODUCT LABELING AND CELL-BASED MEAT

Product labeling has been an evolving topic over the past few years, and therefore, food-labeling litigation has followed suit.[338] Both federal and state courts are now fielding arguments about label claims,[339] the volume of product in drinks,[340] and standards of identity.[341] Therefore, in this Part, we discuss the product labeling of cell-based meat products. In Section III.A, we describe the various opinions on how to label cell-based meat products and proposed federal legislation. In Section III.B, we discuss additional considerations, including comparisons to other labeling controversies like those surrounding plant-based meat and plant-based milk. Then, in Section III.C, we discuss potential issues faced by the cell-based meat industry, including efforts by states to regulate cultivate meat labeling and preemption.

### *A. Cell-based Meat: What's in a Name?*

#### *1. Nomenclature Developments and Battles*

While we are still determining a regulatory scheme on how to safely cultivate meat, there is also no clear consensus on what to even call these products. As mentioned earlier, there is no set nomenclature for meat, poultry, or seafood produced through cellular agriculture,[342] and it appears that the labeling of cell-based meat will be as contentious as the labeling of plant-based meat analogues—if not more so. On one hand, cultivated-meat

---

[338] *Food-Labeling Litigation: Trends to Watch in 2019*, MCGUIREWOODS (Jan. 3, 2019), https://www.mcguirewoods.com/client-resources/Alerts/2019/1/food-labeling-litigation-trends-2019 [https://perma.cc/CKP5-TXCP].

[339] *See, e.g.*, Organic Consumers Ass'n v. Ben & Jerry's Homemade, Inc., No. 2018 CA 004850 B, 2019 D.C. Super LEXIS 1 (D.C. Super. Ct. July 9, 201); Mattero v. Costco Wholesale Corp., 336 F. Supp. 3d 1109 (N.D. Cal. 2018).

[340] *See, e.g.*, Strumlauf v. Starbucks Corp., No. 16-CV-01306-YGR, 2018 WL 306715 (N.D. Cal. Jan. 5, 2018); Forouzesh v. Starbucks Corp., 714 F. App'x 776 (9th Cir. 2018); *see also* Lau v. Pret a Manger (USA) Ltd., No. 1:17-cv-05775, 2018 U.S. Dist. LEXIS 168210 (S.D.N.Y. Sept. 28, 2018) (showing that the misleading volume of food packaging).

[341] *See, e.g.*, Cohen v. East West Tea Co., No. 17-CV-2339-JLS (BLM), 2018 U.S. Dist. LEXIS 130151 (S.D. Cal. Aug. 2, 2018); Peacock v. The 21st Amendment Brewery Cafe, LLC, No.17-CV-01918-JST, 2018 U.S. Dist. LEXIS 7537 (N.D. Cal. Jan. 17, 2018).

[342] Brian P. Sylvester & Nathan A. Beaver, *Your Next Hamburger Could Be "Slaughter-Free,"* NAT'L L. REV. (June 19, 2019), https://www.natlawreview.com/article/your-next-hamburger-could-be-slaughter-free [https://perma.cc/4CY7-RUH2].

producers explain that because meat produced by cellular agriculture is actually "meat," these products should be marketed as such.[343] On the other, the conventional agriculture interests have stated that cell-based meat should not be labeled as meat and that labeling it as such will confuse consumers.[344] According to the formal agreement between FDA and USDA, USDA will take the lead on how industry can label the products, and in a July 31, 2020 announcement we now know that USDA will develop new regulatory requirements for the labeling of cell-based meat and poultry.[345]

AMPS Innovation, a coalition of food companies dedicated to producing meat, poultry and seafood directly from animal cells, includes a guide to terminology on its website. In this guide, the coalition, in addition to using typical meat terms to describe these products, suggests using the terms "cell-based meat," "cultured meat," or "cell-cultured meat" to describe the products.[346] Meanwhile, AMPS Innovation rejects using terms like "clean meat," "lab-grown meat," "fake meat," "synthetic meat," "artificial meat," or "faux meat," as these are terms that are "judgement-based" and do not reflect the compositional or scientific accuracy of the products.[347] On the other hand, "cell-based meat" is arguably not scientifically sound either—cells are the building block of life and are present in conventionally produced meat too.

---

[343] Cameron et al., *supra* note 121 ("Cell-based meat . . . is genuine animal meat that can replicate the sensory and nutritional profile of conventionally produced meat because it's comprised of the same cell types and arranged in the same three-dimensional structure as animal tissue.").

[344] U.S. CATTLEMEN'S ASS'N, PETITION FOR THE IMPOSITION OF BEEF AND MEAT LABELING REQUIREMENTS: TO EXCLUDE PRODUCTS NOT DERIVED DIRECTLY FROM ANIMALS RAISED AND SLAUGHTERED FROM THE DEFINITION OF "BEEF" AND "MEAT" 1 (2018), https://www.fsis.usda.gov/wps/wcm/connect/e4749f95-e79a-4ba5-883b-394c8bdc97a3/18-01-Petition-US-Cattlement-Association020918.pdf?MOD=AJPERES [https://perma.cc/PP4T-65RD] [hereinafter USCA PETITION].

[345] Elaine Watson, USDA to launch rulemaking process for labelling of cell-cultured meat; 'success will turn, in large measure, in the nomenclature used,' says attorney, FOODNAVIGATORR-USA.COM, (Aug. 4, 2020), https://www.foodnavigator-usa.com/Article/2020/08/04/USDA-to-launch-rulemaking-and-public-comment-process-for-labeling-of-cell-cultured-meat [https://perma.cc/2X83-5STC]; *See also,* Kelsey Piper, The lab-grown meat industry just got the regulatory oversight it's been begging for, VOX (March 9, 2019 8:00 AM) https://www.vox.com/future-perfect/2019/3/9/18255806/fda-usda-lab-grown-meat-cell-based-vegan-vegetarian [https://perma.cc/A67S-5Z2L].

[346] *A Guide to Terminology*, ALLIANCE FOR MEAT, POULTRY & SEAFOOD INNOVATION, https://ampsinnovation.org/resources/a-guide-to-terminology/ [https://perma.cc/NNF9-PSD8].

[347] *Id.*

Meanwhile, conventional meat industry interests contend that cell-based meat should not be labeled as meat and that not subjecting cell-based meat to USDA labeling requirements would create an unlevel playing field.[348] In February 2018, the United States Cattlemen's Association ("USCA") filed a petition with USDA-FSIS requesting that the USDA undertake rulemaking on beef labeling to clarify the difference between beef derived from cattle and "beef" products created through cell culture technology.[349] The USCA's petition targets both plant-based meat products, such as the Impossible Burger or Beyond Meat, and "lab grown product from animal cells" by identifying common dictionary and statutory definitions of "meat" and "beef" to argue that "meat" is synonymous with slaughter.[350] Therefore, the petition argues that to label these "alternative products" without "imitation" near "meat" would misbrand the product under the FMIA.[351] To date, the USDA has received over 6,150 comments on this petition.

In response, the Good Food Institute and other supporting organizations, urged the USDA to reject the petition.[352] While the comment focused primarily on plant-based meats, GFI stated that the "basic legal and policy principles . . . would also apply to clean meat, and our comments are intended to inform the agency's thinking on both."[353] GFI argued several points in support of its contention.[354] GFI first contended that USDA *cannot* grant the Cattlemen's petition because the agency does not have authority over the labeling of plant-based products[355] (whereas here, the formal agreement and the definition of meat from formal USDA rulemaking arguably *do* provide USDA authority over cell-based meat).

While the first argument may not directly apply to cell-based meat, GFI's additional arguments apply to both plant-based meat and cell-based meat. GFI stated that the Cattlemen's

---

[348] Sylvester, *supra* note 28.

[349] USCA PETITION, *supra* note 352.

[350] *Id.* at 2; *see also* Mayhall, *supra* note 167, at 167.

[351] USCA PETITION, *supra* note 352, at 2; *see also* Mayhall, *supra* note 167, at 167.

[352] Letter from Jessica Almy, Director of Policy Good Food Inst., to Food Safety & Inspection Service (Apr. 17, 2018), https://www.gfi.org/images/uploads/2018/04/GFIetal-Comment-FSIS-2018-0016.pdf [https://perma.cc/5JNZ-5NDF] [hereinafter GFI RESPONSE].

[353] *Id.* at 2–3.

[354] *Id.*

[355] *Id.* at 4.

proposal is driven by commercial interests and positioning in the marketplace and that USCA has *consistently* refused to favor producers that use different production or processing methods.[356] Next, GFI reminded USDA of the bigger picture: that clear labels, that contain appropriate qualifiers and the nature of the products, are entirely truthful and do not violate the labeling requirements of the FDCA or the FMIA.[357] First Amendment jurisprudence, discussed more below, has a clear framework that in order to restrict truthful commercial speech, the restriction must further a legitimate and substantial government purpose.[358] GFI argues that restricting or requiring particular language for the purpose of "privileging one sector of an industry over another does not qualify" as either legitimate or substantial.[359] Neither the FDA nor the USDA has come out with any changes to the standards of identities or labeling guidance related to cell-based meat.[360]

It remains to be seen what, if any, implications the plant-based meat labeling debate may have for the labeling of cell-based meat products.[361]

*(a) The Real MEAT Act*

Then, in October 2019, Representatives Anthony Brindisi (Dem.) of rural New York and Roger Marshall (Rep.) of Kansas introduced the Real Marketing Edible Artificials Truthfully ("MEAT") Act of 2019, otherwise known as the Real MEAT Act.[362] While this bill did not advance, it is worth discussing here as future bills may seek to mimic its contents. The bill was primarily introduced to address meat analogues made from plant proteins, it has specific language that would affect the labeling of cultured meat products as well. The bill states that "any imitation meat food product, beef, or beef product shall be deemed to be misbranded unless its label bears . . . . the word 'imitation' immediately before

---

[356] *See id.* at 5.

[357] *Id.* at 7.

[358] GFI RESPONSE, *supra* note 360, at 7.; *see also* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564 (1980).

[359] GFI RESPONSE, *supra* note 360, at 7.

[360] Joel L. Greene and Sahar Angadjivand, *Regualtion of Cell-Cultured Meat*, CONG. RES. SERV. (Oct. 25, 2018) https://fas.org/sgp/crs/misc/IF10947.pdf [https://perma.cc/L93R-ZQPL].

[361] U.S. FOOD & DRUG ADMIN., *supra* note 136.

[362] Real MEAT Act, H.R. 4881, 116th Cong. (2019).

or after the name of the food and a statement that clearly indicates that the product is not derived from or does not contain meat."[363] Additionally, the proposed bill defines "beef" or "beef product" as "any product containing edible meat tissue harvested in whole form from domesticated Bos indicus or Bos taurus cattle," which would act to exclude both plant-based and cell-based meat from the definition.[364]

The Real MEAT Act was welcomed by the USCA, who stated that this bill "satisfies part of USCA's ask to USDA FSIS in its 2018 petition for rulemaking defining 'beef' as a product that is derived exclusively from the flesh of bovine animal."[365] The president of the National Cattlemen's Beef Association, Jennifer Houston, commented, "consumers need to be protected from deceptive marketing practices, and cattle producers need to be able to compete on a fair, level playing field."[366]

While the conventional meat industry argues that without this bill there is an "opportunity for marketplace confusion and consumer fraud," the Good Food Institute and other 'new industry' players argue that there is no evidence that consumers are confused by veggie burgers or other products that use qualifiers like "meatless," "vegan," or "plant-based."[367] Instead, they argue that this bill is a "bald-faced attempt to get the government to police food labels to benefit conventional meat industry, not consumers."[368]

If such similar legislation is ultimately passed, it is likely to face significant pushback from industry and face First Amendment challenges guided by the Supreme Court's decision in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.[369] In *Central Hudson*, the Supreme Court affirmed

---

[363] *Id.* at § 403D(a).

[364] *Id.* at § 403D(a)(1).

[365] Greg Henderson, *Real MEAT Act 2019 Introduced*, DROVERS (Oct. 29, 2019, 9:51 AM), https://www.drovers.com/article/real-meat-act-2019-introduced [https://perma.cc/4V4B-ETRW].

[366] *Id.*

[367] Elaine Watson, *The Real MEAT Act 2019: Plant-Based Brands Should Use Term 'Imitation' Meat*, FOOD NAVIGATOR –USA.COM (Oct. 29, 2019), https://www.foodnavigator-usa.com/Article/2019/10/29/The-Real-MEAT-Act-2019-Plant-based-brands-should-use-term-imitation-meat [https://perma.cc/5LP4-LL4K].

[368] *Id.*

[369] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564 (1980).

that the First Amendment protects commercial speech, which includes words on product labels.[370] As mentioned above, the Court explained that there are limits to when the government can restrict commercial speech—when the restriction directly advances a substantial governmental interest and the restriction is not more extensive than necessary to serve that interest.[371] Additionally, restricting commercial speech on a product label would be considered a content-based restriction because the government would be prohibiting speech on the basis of what it says. [372] Content-based restrictions are subject to heightened scrutiny.[373]

The GFI in its response to the Cattlemen's position noted that:

> it would be difficult, if not impossible, to imagine a scenario where the government would meet the high bar of demonstrating that banning names with clear, truthful descriptors (e.g., "plant-based burger patties" or "beefy plant-based protein crumbles") is not an overly restrictive approach to ensure consumer understanding.[374]

Since consumers typically understand the difference between "soymilk" and cow's milk and animal meats and plant-based meats, GFI argued, the First Amendment should protect the rights of cell-based meat as long as the producers accurately describe their products.[375] This argument as to consumer understanding parallels the outcomes in recent district court litigation concerning deceptive-labeling in the context of soymilk, in which courts have tended to dismiss complaints that labeling soymilk as "soymilk" deceives consumers.[376]

---

[370] *Id.* at 574.
[371] *Id.* at 564.
[372] Sorrell v. IMS Health Inc., 564 U.S. 552, 565 (2011).
[373] *Id.*
[374] GFI RESPONSE, *supra* note 360, at 8.
[375] See *id.*
[376] Ang v. Whitewave Foods Company, No. 13-cv-1953, 2013 U.S. Dist. LEXIS 173185 (N.D. Cal. Dec. 10, 2013).

## *B. Considerations for Labeling Laws*

### *1. Crying Over Spilled Milk*

Some observers are noting the similarities between meat (planted based and cultivated) labeling and the plant-based dairy substitute labeling debate. At FDA's July 12, 2018 public meeting on Foods Produced Using Animal Cell Culture Technology, a dairy representative went on record "criticiz[ing] FDA for its ongoing tolerance for labeling terms such as soy and almond 'milk.'"[377] Coincidentally, five days after the meeting, then-Commissioner Gottlieb announced that FDA intended to limit the use of term "milk" when labelling nondairy products.[378] It was in this announcement that then-Commissioner Gottlieb made his now-oft-circulated quip that "[a]n almond doesn't lactate."[379]

Like plant-based and cell-based meat, "milk" has been targeted by industry as misbranded when used to describe plant-based alternatives. Milk has gone beyond the traditional soy and almond,[380] and now there is an influx of alternative milks like oat, hemp, flax, pea, and hazelnut, to name a few.[381] In response to this rising market, several states have begun to adopt "truth in labeling" requirements to prevent those products from calling themselves milk.

Cell-based meat stakeholders stand to gain by understanding the litigation positions put forth by alternative dairy in response to the "Truth in Labeling" laws and apply them to the state laws that affect cell-based meat.

Courts have so far sided definitively against lawsuits alleging that plant-based terms like "soy milk" are misleading. For example, in *Gitson v. Trader Joe's Co.*, the plaintiffs alleged that

---

[377] Sylvester, *supra* note 26.

[378] Evich, *supra* note 166; Sylvester, *supra* note 26.

[379] Alexander Nieves, *Gottlieb: FDA to Crack Down on Labeling Nondairy Products as 'Milk,'* POLITICO (July 17, 2018, 11:25 AM), https://www.politico.com/story/2018/07/17/almond-lactate-nondairy-milk-scott-gottlieb-725974 [https://perma.cc/9S35-RDZE].

[380] *See Flexible Words for Your Favorite Foods*, MERRIAM-WEBSTER, https://www.merriam-webster.com/words-at-play/food-words-additional-meanings [https://perma.cc/YU97-R86X] (explaining that the term for milk has expanded and references to almond milk have dated back to the 15th century). .

[381] *See generally, e.g.*, Bonnie Wertheim, *The Humble Ascent of Oat Milk*, N.Y. TIMES (Jan. 19, 2018), https://www.nytimes.com/2018/01/19/style/oat-milk-coffee-oatly.html [https://perma.cc/4W4U-KYTT].

Trader Joe's had mislabeled products in violation of the FDCA and California law because the plant-based milk product did not contain cow's milk.[382] But the court held that Plaintiff did not state a claim with regard to "soymilk" because such labeling did not violate the FDCA at all.[383] In the opinion, the court noted that from a "reasonable consumer" perspective, the plaintiffs did not "articulate[] a plausible explanation for how 'soymilk' is misleading."[384] Stated the court: "The reasonable consumer (indeed, even the least sophisticated consumer) does not think soymilk comes from a cow. To the contrary, people drink soymilk in lieu of cow's milk."[385] Regarding potential consumer confusion in nutritional differences, "if the consumer cared about the nutritional content, she would consult the label."[386] The court also addressed whether the soymilk purported to be or is represented as a standard of identity:

> The fact that the FDA has standardized milk does not categorically preclude a company from giving any food product a name that includes the word 'milk.' Rather . . . a company cannot *pass off* a product as 'milk' if it does not meet the regulatory definition . . . Soymilk, in short, does not 'purport[] to be' from a cow . . . .[387]

Similarly, in *Painter v. Blue Diamond Growers*, a court dismissed a lawsuit alleging that almond milk marketing was misleading on the basis that consumers falsely believed that almond milk had the same nutritional profile as dairy milk.[388] The opinion stated that "no reasonable consumer could be misled by Defendant's unambiguous labeling and factually accurate nutrition statements . . . by using the term '*almond milk*,' even the

---

[382] Gitson v. Trader Joe's Co., No. 13-cv-01333-VC, 2015 U.S. Dist. LEXIS 170401, at *1-2 (N.D. Cal. Dec. 1, 2015).

[383] *Id.* at. *7–8.

[384] *Id.* at *3-4.

[385] *Id.* at *4.

[386] *Id.*

[387] *Id.*

[388] Painter v. Blue Diamond Growers, No. Civ-17-02235-SVW-AJW, 2017 U.S. Dist. LEXIS 215086 (C.D. Cal. May 24, 2017).

least sophisticated consumer would know instantly the type of product they are purchasing."[389]

The soymilk and almond milk cases have led the way in court battles guiding how courts view misbranding and standards of identity. As opposed to plant-based dairy products, cell-based meat arguably has a stronger stance in the courtroom, since cell-based meat *is* arguably meat, and it is wise to look to these cases as guidance. On the other hand, cell-based meat's similarity to conventional meat might risk raising "passing off" concerns that the courts above disregarded for soymilk.

### *2. The Role of Dictionaries*

The labeling controversy highlights not only the emotional importance of labels but prompts an examination of the proper role of dictionaries as a guide to legislation and regulation, especially for innovative technologies. Both the USCA's petition with USDA and GFI's response use dictionaries to bolster their arguments, but are dictionaries meant for this analysis—and to what extent?

English, unlike languages such as French, has no official rules or governing bodies. Better said, "English, like any other language, is a geopolitical phenomenon that evolves by way of individual genius."[390] Because of this, our language is always growing. According to Global Language Monitor, around 5,400 new words are created every year through one of 13 different mechanisms.[391] One of those mechanisms is "repurposing" or taking a word from one context and applying it to another.[392] For example, in September 2019, Merriam-Webster added 533 new words and new meanings to its dictionary and included more than 400 other revisions to definitions, etymologies, pronunciations, and dates of first known use.[393]

---

[389] *Id.* at *6–7.

[390] Megan Garber, *The Case Against the Grammar Scolds*, ATLANTIC (March 16, 2017), https://www.theatlantic.com/entertainment/archive/2017/03/the-case-against-the-grammar-scolds/519552/ [https://perma.cc/WDG5-YRKH].

[391] Andy Bodle, *How New Words Are Born*, GUARDIAN (Feb. 4, 2016), https://www.theguardian.com/media/mind-your-language/2016/feb/04/english-neologisms-new-words [https://perma.cc/6EVE-LA7G].

[392] *Id.*

[393] *We Added New Words to the Dictionary for September 2019*, MERRIAM-WEBSTER, https://www.merriam-webster.com/words-at-play/new-words-in-the-dictionary [https://perma.cc/7HXZ-24N6].

Legislation is by nature prospective. But, dictionaries are the opposite. Dictionaries reflect the past or modern meaning of words, rather than being able to look into the future.[394] Further, editorial philosophies behind dictionaries have a strong influence on the content of definitions and the relationships between definitions and actual usage: consider, for instance, the monumental schism in the writing community over the prescriptivist *Webster's Second* (which, loosely speaking, defined how words *should* be used) and the descriptivist *Webster's Third* (which sought to define how words *are* used).[395] How many litigants or advocates appreciate or consider these differences?[396] Jesse Sheidlower, the former editor-at-large of the *Oxford English Dictionary*, once said, "I think that it's probably wrong, in almost all situations, to use a dictionary in the courtroom… Dictionary definitions are written with a lot of things in mind, but rigorously circumscribing the exact meanings and connotations of terms is not usually one of them."[397] When lawyers, legislators, and the courts use dictionaries to guide the law, J. Gordon Christy noted, "we are treated to the truly absurd spectacle of august justices and judges arguing over which unreliable dictionary and which unreliable dictionary definition should be deemed authoritative."[398] In a 1945 decision, Judge Hand reminded us that "statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning;"[399] essentially, that the Court should not use dictionaries to discover what Congress intended words to mean.

Further, dictionaries do not create the definition of words and are not meant to determine the outer boundaries of a word's

---

[394] *See generally* KORY STAMPER, WORD BY WORD: THE SECRET LIFE OF DICTIONARIES (2017) (describing how dictionaries are produced).

[395] *See, e.g.*, Mike Vuolo, *The Story of* Ain't*,* SLATE: LEXICON VALLEY (Mar. 5, 2012: 2:12 PM), http://www.slate.com/articles/podcasts/lexicon_valley/2012/03/lexicon_valley_webster_s_third_the_most_controversial_dictionary_ever_published_.html [https://perma.cc/UZ3X-PWXK].

[396] *See, e.g.*, *Antonin Scalia v. Merriam-Webster*, MERRIAM-WEBSTER, https://www.merriam-webster.com/words-at-play/antonin-scalia-v-merriam-webster [https://perma.cc/Y699-YTGN] (suggesting that jurists take this difference very seriously).

[397] Adam Liptak, *Justices Turning More Frequently to Dictionary, and Not Just for Big Words,* N.Y. TIMES (June 13, 2011) https://www.nytimes.com/2011/06/14/us/14bar.html [https://perma.cc/4C4U-JLHF].

[398] *Id.*

[399] *Id.*

applicability.[400] In the world of ever-changing technology and continually re-defining the bounds of how we create food, we should be cautious of using dictionaries, since they are by definition acontextual. Dictionaries do not put words in context, nor do they represent all the possible meanings of words. Instead, words should be "interpreted in light of the context in which it occurs and its place in the overall statutory scheme,"[401] which includes the innovation of technology which gives new context to "beef" and "meat" which could not be encapsulated in Merriam-Webster or dictionary.com.

### *C. Possible Concerns*

#### *1. State Legislation*

The labeling conversations are not only happening at the federal level, but also on a state level with various state legislation seeking to limit the use of meat or add qualifiers before or after "meat." In 2019 alone, eleven states passed labeling laws and sixteen states proposed legislation that targeted both plant-based and cell-based meat labeling.[402] Several of these laws provide that only foods derived from food-producing animals may bear labels like "meat," "sausage," "jerky," "burger," or other "meaty" terms.[403]

Missouri, the first state to do so, passed a law limiting the use of the term meat in 2018.[404] The law altered that state's Meat Advertising Law "to prohibit the representation of a product as meat when the product 'is not derived from harvested production livestock or poultry.'"[405] Since 2018, several other states passed similar legislation concerning labeling laws and the term meat. This includes Alabama, Arkansas, Kentucky, Louisiana,

---

[400] Pamela Hobbs, *Defining the Law: (Mis)using the Dictionary to Decide Cases*, 13, 328 DISCOURSE STUDIES 327 (2011).

[401] *Id.* at 344.

[402] Elaine Watson, *Plant-based and cell-cultures 'meat' labeling under attack in 25 States*, FOODNAVIGATOR-USA.COM (May 23, 2019) https://www.foodnavigator-usa.com/Article/2019/05/29/Plant-based-and-cell-cultured-meat-labeling-under-attack-in-25-states [https://perma.cc/R74T-5Q7V].

[403] *Id.*

[404] Nathan A. Beaver & Bryan P. Sylvester, *What's in a Name? The Plant-Based Foods Labeling Debate*, FOLEY (Oct. 8, 2019), https://www.foley.com/en/insights/publications/2019/10/whats-in-a-name-plant-based-foods-labeling-debate [https://perma.cc/ACE4-2YFM].

[405] *Id.*

Mississippi, Montana, North Dakota, Oklahoma, South Carolina, South Dakota, and Wyoming.[406] Many of these new laws result in criminal prosecution if there is a violation.[407]

According to certain States' clarifications, products will not be mislabeled if the labels clearly indicate the product is plant based.[408] Missouri law does not consider a product to be mislabeled if the label contains:

> A prominent statement on the front of the package, immediately before or immediately after the product name, that the product is "plant-based," "veggie," "lab-grown," "lab-created," or a comparable qualifier; and
> A prominent statement on the package that the product is "made from plants," "grown in a lab," or a comparable disclosure.[409]

In September 2019, the Mississippi Department of Agriculture rolled out new regulations to implement the state's labeling law that would allow the use of meat and meat product terms on the labels of plant-based food under prescribed conditions. [410]

Missouri and Mississippi's clarifications conform with federal law. [411] In other words, if the label "accurately describes the properties of a given food and is not otherwise false or misleading, a food is typically eligible to bear the desired term."[412] It follows that a plant-based burger can use the term "burger" provided there is clear labeling that the product is plant-based.[413]

Yet, the new legislations have not gone unchallenged. The ACLU, the Good Food Institute, Tofurky, and the Animal Legal Defense Fund are actively challenging these laws.[414] In *Turtle*

---

[406] *Id.*
[407] *Id.*
[408] *Id.*
[409] Memorandum from Director's Office of the Department of Agriculture on Missouri's Meat Advertising Law to Meat Inspection Program (Aug. 30, 2018), https://agriculture.mo.gov/animals/pdf/missouri-meat-advertising-guidance.pdf [https://perma.cc/NG72-CN4D].
[410] Beaver & Sylvester, *supra* note 414.
[411] *Id.*
[412] *Id.*
[413] *Id.*
[414] *See,* Watson, *supra* note 412.

*Island Food v. Richardson*, the plaintiffs challenged Missouri's Meat Advertising law as violating the Free Speech Clause of the First Amendment, the Dormant Commerce Clause, and the Due Process Clause.[415] The Missouri trial judge ruled against the plaintiffs and denied their request for preliminary injunction to prevent Missouri from enforcing the law—therefore, the judge's ruling remains in place while the litigation goes forward.[416]

In this case, the federal judge found that:

> the plaintiffs are unlikely to succeed on the First Amendment claim as applied to them, because the statute only prohibits speech which would be misleading, and this is a permissible government restriction. Additionally, the state argues that the plaintiffs are unlikely to succeed on a facial challenge to the statute. A facial challenge 'must establish that no set of circumstances exists under which the Act would be valid'… Thus, plaintiffs have not shown that they are at any risk of either prosecution for violating the statute or that there is any need to change their labels or advocacy efforts.[417]

Meanwhile, the plaintiffs brought suit against Arkansas's meat labeling law.[418] Arkansas's meat labeling law makes it illegal for companies to use words like "burger," "sausage," and "roast" to describe products that are not made from animals.[419] In *Turtle Island Food v. Soman*, the plaintiffs similarly challenged Arkansas's censorship law as violating the First Amendment, Dormant Commerce Clause, and Fourteenth Amendment's Due Process Clause by improperly censoring truthful speech and creating consumer confusion in order to shore up the state's meat

---

[415] Turtle Island Foods v. Richardson, No. 2:18-CV-04173, 2019 WL 7546586, at *2 (W.D. Mo. Sep. 30, 2019).

[416] *Id.*

[417] *Id.* at *17-22.

[418] *See* ARK. CODE ANN. § 2-1-305 (2019).

[419] *Id.*

and other industries.[420] Here, the state is arguing that the law is necessary because consumers can be confused about whether a veggie burger comes from a cow.[421] On the other hand, the plaintiffs argue that the state could not identify any evidence that consumers are confused about plant-based products.[422] In this case, the federal court granted the plaintiff's motion to block the Arkansas law while the underlying challenge proceeds.[423]

In both of these cases, the plaintiffs were the same and the challenges were the same—and yet, the courts came out differently. These are just two examples of how, until the federal government provides clear standards or guidance, each state may have different interpretations of "misbranded" under federal and state laws.

### *2. Preemption*

In the background of all of these cases lurks a claim of federal preemption. Federal preemption is based on the Supremacy Clause of the U.S. Constitution[424]—essentially, when state law and federal law conflict, the state law is invalid. There are three main types of preemption: express preemption,[425] field preemption,[426] and conflict preemption.[427]

In the "meat" space, both the FMIA and the PPIA explicitly state that marking, labeling and ingredient requirements in addition to or different than those required under the FMIA and the PPIA may not be imposed by any state or territory.[428] This federal preemption stance has previously been invoked by the meat and poultry industries to invalidate prior state and local initiatives. Consumer protection statutes are the most-used way

---

[420] Turtle Island Foods SPC v. Soman, 424 F. Supp 3d 552, 561 (E.D. Ark. Dec. 11, 2019).

[421] *Id.* at 563.

[422] *Id.* at 575.

[423] *Id.* at 579.

[424] U.S. CONST. art. VI, cl. 2.

[425] *Virginia Uranium*, 139 S. Ct. at 1901

[426] *Id.*

[427] *Id.*

[428] 21 U.S.C. § 678 (2018); *see id.* § 467(e); *see also* Robert Hibbert & Amaru Sanchez, *State Meat Label Restrictions Face Preemption Challenges*, LAW360 (March 6, 2019, 2:37 PM), https://www.law360.com/articles/1135648/state-meat-label-restrictions-face-preemption-challenges [https://perma.cc/F6JK-HTXZ].

for pursuing private food labeling actions and enforcing purported "'identical' state standards."[429]

In *Armour v. Ball*, two meat producers brought an action against Michigan state officials alleging that Michigan's state law imposed additional or different marking, labeling, packaging, and ingredient provisions than the FMIA.[430] The court agreed, holding that under the Supremacy Clause, the FMIA preempted provisions of the Michigan law.[431]

Nevertheless, this provision has not been successful as a catch-all to prevent state legislatures from expanding state labeling laws. In 2010, in *Zupnik v. Tropicana Products, Inc.,* a court permitted suit for a false or misleading label, reasoning that if the Food and Drug Administration can sue for false or misleading labels, then a private party equipped with a private right of action under state law can sue to enforce an identical state statute.[432] The court in *Zupnick* determined that federal law did not preempt the state law claims "[b]ecause Congress has also allowed states, at the very least, to pass statutes identical to [federal law."[433] Yet, in a subsequent case, *Henry v. Gerber Products Co.*, a court rejected the *Zupnik* court's reasoning and concluded that the FDCA preempted a state-law consumer protection claim alleging that the labels for Gerber's Graduate Puffs were misleading because the cereal snacks did not contain any fruits or vegetables despite photos of bananas and sweet potatoes.[434] The Court found that regulations implemented under the FDCA authorize manufacturers to use the name and image of a fruit on a product's packaging to describe its characterizing

---

[429] James M. Beck, *Food Fight: FDA Preemption and Food Labeling Claims*, LAW360 (Jan. 27, 2011, 2:14 PM), https://www.law360.com/articles/221444/food-fight-fda-preemption-and-food-labeling-claims [https://perma.cc/DF9N-2X22].

[430] Armour & Co. v. Ball, 468 F.2d 76 (6th Cir. 1972).

[431] *Id.* at 85.

[432] *See* Zupnik v. Tropicana Products, No. CV 09-6130 DSF, 2010 WL 6090604 (C.D. Cal. Feb. 1, 2010).

[433] *Id.*

[434] Henry v. Gerber Prods. Co., No. 3:15-CV-02201-HZ, 2016 WL 1589900, at *20 (D. Or. Apr. 18, 2016); s*ee also* Arnold & Porter Kaye Scholer LLP, *Oregon Court Finds FDA Food Labeling Regulations Preempt State Consumer Protection Suit*, LEXOLOGY (June 13, 2016), https://www.lexology.com/library/detail.aspx?g=02fcb592-f25d-4bc0-a4b1-f8e8cb345e10 [https://perma.cc/7KGJ-2GJ2]

flavor even when the product itself does not actually contain any of the depicted fruit.[435]

Looking ahead, it remains to be seen how federal preemption will be interpreted in the cell-based meat context.

### *3. Other Labeling Concerns*

In addition to labeling concerns for what to call the entire cell-based meat product, there are additional labeling questions that will need to be addressed. One example is how to label allergens that may carry over into cultured meat from the production system. Similarly, how to describe the nutritional composition of cell-based meat as compared to conventionally produced meat, especially for cultured products that contain enhanced levels of micronutrients.

While naming the product is one of the current controversies, there are several other battles ahead on what should (and should not) appear on the labels of cell-based meat.

## CONCLUSION

The pathway to cell-based meat appearing in the market in the United States is open; FDA and the USDA will jointly oversee the evolution of regulation of this cutting-edge food technology. Overall, there is a viable pathway forward for cultivated-meat companies under the current regulatory scheme. But a nontrivial degree of uncertainty remains, and regulators would do well to be proactive in issuing guidance in this space.

---

[435] *Henry*, 2016 WL 1589900, at *20.