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U.S. Department of Agriculture
Food Safety and Inspection Service
Attention: Mr. Paul Kiecker, Administrator
1400 Independence Avenue, SW
Washington, D.C. 20250-3700

June 9, 2020

Dear Administrator Kiecker,

The Harvard Law School Animal Law & Policy Clinic writes to respectfully urge the U.S. Department of Agriculture to adopt a labeling approach for cell-based meat and poultry products that does not overly restrict speech and that respects the First Amendment. The Animal Law & Policy Clinic (“ALPC”) undertakes work in the area of animal law and policy, domestically and internationally, and focuses on high-impact opportunities to improve the treatment of animals through litigation, policy analysis, and applied academic research. As part of this work, ALPC closely monitors technological developments within the food sector that have the potential to affect animals. Cell-based meat and poultry products (hereinafter referred to collectively as “cell-based meat,”¹ also known as “cultured” or “cultivated” meat) are such innovations in food, with tremendous potential to positively impact animals, human health, and environmental sustainability. As U.S. Department of Agriculture (“USDA”) Secretary Perdue envisions, cell-based meat could even offer a way to meet the tremendous protein needs of the growing global population.²

¹ This letter will use the term “cell-based meat” to encompass cell-based meat, poultry, and fish products derived from any USDA-amenable species, including catfish.

² See Remarks by USDA Secretary Perdue, USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry, Day 1 Morning Session Transcript (Oct. 23, 2018), <https://www.fsis.usda.gov/wps/wcm/connect/42c8b917-8c01-459d-8aa3-51e0b67ae84a/transcript-cellular-agriculture-day1-morning-102318.pdf?MOD=AJPERES> (noting that “we’ll need to produce the same amount of food . . . over the next 50 years as we have in the history of civilization” and asserting that there will be “nine billion hungry souls and that means we must feed them, wherever they are, by whatever means are available and necessary. . . . [I]ncluding new technology like cell cultured meat.”).

While the regulatory pathway for cell-based meats is not yet entirely defined, the U.S. Department of Agriculture Food Safety and Inspection Service (“USDA-FSIS”) has recognized cell-based meat and poultry products as “meat” and “poultry” products under its governing statutes,³ has asserted jurisdiction over labeling for such products,⁴ and is in the process of drafting labeling regulations for cell-based meats.⁵ It is at this juncture that ALPC writes to urge USDA-FSIS to adopt a labeling approach that does not overly restrict speech and respects the protections afforded to commercial speech under the First Amendment. As detailed extensively below, a ban on the use of common or standardized meat and poultry terms on non-misleading cell-based meat labels is likely unconstitutional, as are labeling restrictions that are more extensive than necessary. USDA-FSIS should wait until it has a better understanding of the composition and safety of finished cell-based meat products and an opportunity to review proposed labels before establishing speech restrictions that raise constitutional questions. By delaying the establishment of restrictive labeling requirements, USDA-FSIS will be able to assess whether, or to what extent, such speech restrictions are actually necessary in order to protect consumers from being misled. Further, USDA-FSIS should only compel process-based disclosures or qualifiers on cell-based meat labels on a case-by-case basis when doing so is necessary to protect consumers from an increased food safety risk or material compositional difference.

A labeling scheme that does not ban the use of common or usual meat and poultry terms or product names on cell-based meat products and that only requires disclosures when necessary to protect consumers is consistent with longstanding USDA policy, prioritizes consumer safety while preserving consumer choice, and enables these American innovations to compete fairly. Conversely, a labeling scheme that bans the use of such food terms in the labeling of cell-based meat products or that requires disclosures unnecessarily likely violates the First Amendment and may be deemed arbitrary and capricious under the Administrative Procedure Act. Such restrictions also could create consumer confusion, stifle promising innovation, and drive companies abroad. Finally, ALPC believes that new standards of identity are not necessary to establish such a labeling regime and requests that USDA-FSIS consult with the U.S. Department of Health and Human Services Food and Drug Administration (“HHS-FDA”) in order to ensure regulatory consistency for cell-based meat and seafood products, as required by the Federal Meat Inspection Act (“FMIA”) and the Poultry Product Inspection Act (“PPIA”).⁶

³ USDA & U.S. FOOD & DRUG ADMIN., STATEMENT FROM USDA SECRETARY PERDUE AND FDA COMMISSIONER GOTTLIEB ON THE REGULATION OF CELL-CULTURED FOOD PRODUCTS FROM CELL LINES OF LIVESTOCK AND POULTRY (Nov. 16, 2018), <https://www.fda.gov/news-events/press-announcements/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb-regulation-cell-cultured-food-products> [hereinafter STATEMENT FROM USDA SECRETARY PERDUE AND FDA COMMISSIONER GOTTLIEB]; USDA & U.S. FOOD & DRUG ADMIN., AGREEMENT BETWEEN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION AND U.S. DEPARTMENT OF AGRICULTURE OFFICE OF FOOD SAFETY 1–3 (Mar. 8, 2019), <https://www.fsis.usda.gov/formalagreement> [hereinafter FORMAL AGREEMENT].

⁴ FORMAL AGREEMENT, *supra* note 3.

⁵ See Remarks by Rosalyn Murphy-Jenkins, Director of Labeling and Program Delivery Staff, Office of Policy and Program Development, USDA-FSIS, at FDA Public Meeting for Horizontal Approaches to Food Standards of Identity Modernization, Transcript (Sept. 27, 2019) <https://www.fda.gov/media/131428/download>.

⁶ See 21 U.S.C. §§ 607(c), 457(b) (prohibiting USDA from establishing standards of identity under the FMIA or the PPIA that are “inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act,” and requiring USDA to consult with HHS-FDA “prior to the issuance of such standards . . . to avoid inconsistency in such standards and possible impairment of the coordinated effective administration of these Acts”).

I. Background

The idea of growing real meat without slaughtering an animal still feels like science fiction to many, but ninety years since it was first envisioned,⁷ cell-based meat is nearing market reality. The technology underlying cell-based meat has been in development for decades, with the first patent awarded for cell-based meat by the European Union in 1999 to a physician, Willem van Eelen.⁸ After the much-discussed reveal of the first cell-based hamburger by Mark Post and his team in 2013,⁹ interest and investment in the development of cell-based meat has risen exponentially.¹⁰ There has been a proliferation of companies working to produce meat using cell-based processes and to reduce the demand for meat from slaughtered animals (“slaughter-based meat”).¹¹ Today, several cell-based meat companies claim that they are ready, or soon will be ready, to introduce their cell-based meat products into the market.¹² While USDA-FSIS and HHS-FDA have made remarkable progress toward clarifying the regulatory pathway for cell-based meat through the agreement the two agencies reached in March 2019, many details remain uncertain, particularly around labeling.

Cell-based meats are likely to be more environmentally sustainable, healthy, and humane versions of America’s favorite proteins. Although precise calculations are unavailable, cell-based meat is predicted to require less energy, significantly less water, and almost no land to produce, as well as produce far fewer greenhouse gas emissions than slaughter-based meat.¹³ Cell-based meat also will be free of all fecal contamination and related pathogens common to slaughter-based meat.¹⁴ It further may have the potential to provide more favorable nutritional profiles than

⁷ Brian J. Ford, *Culturing Meat for The Future: Anti-Death Versus Anti-Life*, in 7 DEATH AND ANTI-DEATH 2 (Charles Tandy ed., 2010) (citing FREDERICK EDWIN SMITH, EARL OF BIRKENHEAD, *THE WORLD IN 2030 A.D.* (London, Hodder & Stoughton 1930)).

⁸ PAUL SHAPIRO, CLEAN MEAT 40–41 (2018).

⁹ *First Lab-Grown Hamburger Gets Full Marks for ‘Mouth Feel,’* THE GUARDIAN (Aug. 5, 2013), <https://www.theguardian.com/science/2013/aug/05/world-first-synthetic-hamburger-mouth-feel>.

¹⁰ See, e.g., *State of the Industry Reports*, GOOD FOOD INSTITUTE, 2019, <https://www.gfi.org/industry> (noting a 160% increase in the number of investments and greater than 200% increase in the amount of capital invested deals in cell-based meat companies in 2018 alone).

¹¹ See, e.g., *Investors Capitalize on a Global Shift in Meat Production*, GOOD FOOD INSTITUTE (May 6, 2019), <https://www.gfi.org/record-investment-media-statement> (noting a 68% increase in the number of cell-based meat companies in 2018).

¹² On November 3, 2019, David Kay, Senior Manager of Communications for Memphis Meats, publicly stated at the Harvard Business School Food & Agriculture Conference that Memphis Meats (a cell-based meat start-up company) is ready to begin selling its products to the public on a small scale and that the only barrier preventing the company from doing so is the current lack of a clearly defined regulatory pathway. Just Inc., another cell-based meat company, has publicly made similar assertions. See *Lab-Meat Growers Wants Help From Industry They Seek to Disrupt*, BLOOMBERG (Nov. 25, 2018), <https://www.bloomberg.com/news/articles/2018-11-26/lab-meat-growers-seek-help-from-industry-they-seek-to-disrupt>.

¹³ See, e.g., Hanna L. Tuomisto & M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, 45 ENVTL. SCI. & TECH. 6117 (2011), <http://dx.doi.org/10.1021/es200130u>; Zhi-chang Sun, Qun-li Yu & Lin Han, *The Environmental Prospects of Cultured Meat in China*, 14 J. INTEGRATIVE AGRIC. 234 (2015) [https://doi.org/10.1016/S2095-3119\(14\)60891-1](https://doi.org/10.1016/S2095-3119(14)60891-1); Carolyn S. Mattick, Amy E. Landis & Braden R. Allenby, *A Case for Systemic Environmental Analysis of Cultured Meat*, J. INTEGRATIVE AGRIC. 14, at 249, 252 (2015).

¹⁴ Cell-based meat products will be developed without intestinal tracks and thus without exposure to fecal contamination. See generally PAUL SHAPIRO, CLEAN MEAT (2018) (describing the production of cell-based meat); see also D.J. Siegelbaum, *In Search of a Test-Tube Hamburger*, TIME (Apr. 23, 2008), <http://content.time.com/time/health/article/0,8599,1734630,00.html> (“Creating the meat in a lab also decreases its

slaughter-based meat, leading to improved human health.¹⁵ Additionally, by its very nature, cell-based meat will reduce the need to breed, raise, and slaughter animals.¹⁶ Its adoption has the potential to significantly reduce animal suffering.¹⁷

The promise of these environmental, health, and animal welfare benefits, in addition to the potential of increased local food security, has led to international interest and investment by foreign governments.¹⁸ In 2018, the possibilities of cell-based meat even led Tom Hayes, then-CEO of Tyson Foods, the largest producer of meat in the United States, to query, “[i]f we can grow the meat without the animal, why wouldn’t we?”¹⁹ While some cell-based meat start-ups are located internationally, many of the current cell-based meat companies are based in the United States and are poised to launch innovative American agricultural products.²⁰ Indeed, several American cell-based meat companies publicly claim to have been offered generous financial incentives by foreign governments in attempts to lure them abroad.²¹ Although ALPC is unaware of any companies that have left the U.S to establish their businesses elsewhere, cell-based meat companies are likely to accept such offers in the future if regulation in the United States becomes prohibitively onerous.²²

exposure to bacteria and disease, which have riddled the livestock industry, injuring consumers and causing extensive meat recalls.”).

¹⁵ See, e.g., Z.F. Bhat & Hina Bhat, *Animal-free Meat Biofabrication*, 6 AM. J. FOOD TECH. 441, 452 (2011), <http://scialert.net/abstract/?doi=ajft.2011.441.459> (“[H]ealth aspects of the [cell-based] meat can be enhanced . . .”).

¹⁶ See, e.g., DAVID JULIAN MCCLEMENTS, *FUTURE FOODS: HOW MODERN SCIENCE IS TRANSFORMING THE WAY WE EAT* 337 (2019) (“[T]he fact that [cell-based] meat does not involve the large-scale breeding, housing, and slaughtering of animals makes it much more ethical than conventional meat.”); Carolyn S. Mattick, Amy E. Landis & Braden R. Allenby, *A Case for Systemic Environmental Analysis of Cultured Meat*, J. INTEGRATIVE AGRIC. 14, at 249, 252 (2015); Z.F. Bhat & Hina Bhat, *Animal-Free Meat Biofabrication*, 6 AM. J. FOOD TECH. 441, 453 (2011), <http://scialert.net/abstract/?doi=ajft.2011.441.459> (“[A cell-based meat] system reduces animal use in the meat production system . . .”).

¹⁷ Cell-based meat does not raise the same ethical and moral questions that slaughter-based animal agriculture does because cells cultured in vitro do not have a nervous system and are thus unable to feel pain. See, e.g., Carolyn S. Mattick, Amy E. Landis & Braden R. Allenby, *A Case for Systemic Environmental Analysis of Cultured Meat*, J. INTEGRATIVE AGRIC. 14, at 249, 252 (2015) (“Cultured meat presents opportunities to enhance human well-being, reduce animal suffering, and mitigate at least some of the environmental impacts associated with food production.”); Matthew Lincicum, *Synthetic Meat: An Ethical, Environmental, and Regulatory Analysis* 14 (Mar. 29, 2010) (unpublished student paper, Harvard Law School) (on file with Harvard Law School), <http://nrs.harvard.edu/urn-3:HUL.InstRepos:8789567>.

¹⁸ See, e.g., Ramya Ramamurthy, *Indian Government Grants Over \$600,00 to Cell-Based Meat Research* (Apr. 26, 2019), <https://www.gfi.org/2019-04-26>.

¹⁹ *Tyson Isn’t Chicken*, BLOOMBERG BUSINESSWEEK (Aug. 16, 2018), <https://www.bloombergquint.com/businessweek/tyson-s-quest-to-be-your-one-stop-protein-shop> (quoting Tom Hayes).

²⁰ Some of these companies include Memphis Meats, JUST Inc., and Finless Foods.

²¹ See, e.g., Oral comment made by Brian Spears, Co-Founder and CEO of New Age Meats (Oct. 24, 2018), USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry. Transcript from day 2, afternoon session, on page 9, <https://www.fsis.usda.gov/wps/wcm/connect/80a3da71-34f3-4b15-a970-ab5538170f32/transcript-cellular-agriculture-day2-afternoon-102418.pdf?MOD=AJPERES>.

²² At least one start-up, Just Inc., has previously discussed debuting its cell-based products abroad due to the lack of a regulatory pathway in the United States. See *Lab-Meat Growers Wants Help from Industry They Seek to Disrupt*, BLOOMBERG (Nov. 25, 2018), <https://www.bloomberg.com/news/articles/2018-11-26/lab-meat-growers-seek-help-from-industry-they-seek-to-disrupt>.

As USDA Secretary Perdue affirmed, “the United States is leading in this area.”²³ Overly restrictive labeling requirements for cell-based meat products will likely drive innovation abroad and put the U.S. at risk of losing its leadership status in the cellular agriculture field. In order to preserve America’s leadership in this promising field and advantageous position for future global export,²⁴ USDA-FSIS should carefully weigh the benefits of any labeling approach against the potential for that regulation to stifle innovation. Moreover, unnecessarily restrictive labeling requirements likely will violate commercial speech protections. USDA-FSIS should adopt a labeling approach that withstands First Amendment scrutiny and satisfies the Administrative Procedure Act, as discussed in depth below.

II. Current Legal Status of Cell-Based Meat

Currently, USDA-FSIS and HHS-FDA are refining the details of the regulatory pathway for cell-based meat products, and companies are not yet selling these products, which are still under development. Simultaneously, new state-level legislative efforts to restrict labeling are creating legal uncertainty for producers and presenting potentially troubling barriers to market. At least a dozen states have now passed laws that restrict the use of certain terms related to meat on foods not derived from slaughtered animals, including plant-based and cell-based meat.²⁵ These laws prohibit the use of terms like “hamburger” and “sausage” for all but slaughter-based meat products.²⁶ With varying, but often steep, criminal and civil penalties for each violation,²⁷ such laws aim to thwart innovation and create consumer confusion by limiting the ability of producers to accurately describe products and their uses in terms that are familiar to consumers. Although state lawmakers continue to propose similar labeling laws in additional states,²⁸ under the FMIA²⁹ and the PPIA,³⁰ USDA has labeling jurisdiction over animal-based meat, which includes slaughter-based meat and cell-based meat. Both the FMIA and the PPIA prevent states “from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry

²³ Remarks by USDA Secretary Perdue, *supra* note 2 (noting that “the United States is leading in this area . . . and we want to be true world leaders on this topic as we have a challenge to feed the world”).

²⁴ The U.S. government, together with other nations, has noted that “[r]egulatory approaches related to agricultural technologies should be science-based,” and that “[r]estrictions specifically aimed at food from the progeny of clones — such as bans or labeling requirements — could have negative impacts on international trade.” USDA, JOINT STATEMENT ON ANIMAL CLONING FOR LIVESTOCK PRODUCTION (Mar. 16, 2011), <https://www.fas.usda.gov/joint-statement-animal-cloning-livestock-production>. Similarly, a cell-based meat labeling approach should be science-based. Further, restrictive labeling requirements on cell-based meat could decrease trade.

²⁵ See, e.g., *2019 Enacted and Adopted Bills by Topic Map, Food and Food Safety*, NATIONAL CONFERENCE ON STATE LEGISLATURES (Mar. 25, 2020), <https://www.ncsl.org/research/environment-and-natural-resources/environmental-health-legislation-database.aspx>; Alina Selyukh, *What Gets to Be A ‘Burger’? States Restrict Labels on Plant-Based Meat*, NPR (July 23, 2019), <https://www.npr.org/sections/thesalt/2019/07/23/744083270/what-gets-to-be-a-burger-states-restrict-labels-on-plant-based-meat>.

²⁶ See, e.g., *States Attempt to Criminalize Using “Meat” on Cell-Based Meat Labels*, GOOD FOOD INSTITUTE (Mar. 12, 2019), <https://www.gfi.org/states-attempt-to-criminalize-using-meat>.

²⁷ See, e.g., MO. REV. STAT. § 265.494(7), 496 (“misrepresenting a product as meat that is not derived from harvested production livestock or poultry” constitutes a Class A misdemeanor), <https://revisor.mo.gov/main/OneSection.aspx?section=265.496&bid=14356&hl=>; ARK. CODE ANN. § 2-1-306(a)(1) (2019) (fining violators \$1,000 for each violation of ban on the use of meat terms on cell-based meat).

²⁸ See, e.g., WIS. ASSEMBLY BILL 518, <https://docs.legis.wisconsin.gov/2019/proposals/reg/asm/bill/ab518>.

²⁹ 21 U.S.C. 601, *et seq.*

³⁰ 21 U.S.C. 451, *et seq.* See statutory definitions provided at 21 U.S.C. § 601(j) and 21 U.S.C. § 453 (e)–(f).

products that are in addition to, or different than, those imposed under the FMIA or the PPIA.”³¹ As a result, a clear labeling scheme established by USDA-FSIS will preempt state cell-based meat labeling laws that go further than, or differ from, requirements imposed by USDA-FSIS.³² HHS-FDA has jurisdiction over most other foods, including plant-based meat alternatives, as well as drugs and other products, under the Federal Food, Drug, and Cosmetic Act (“FFDCA”),³³ the Public Health Service Act,³⁴ and the Fair Packaging and Labeling Act.³⁵ HHS-FDA has concurrent jurisdiction with USDA-FSIS over establishing meat and poultry standards of identity and, as noted above, USDA-FSIS must consult with HHS-FDA on any new standards.³⁶ Under the FMIA and the PPIA, standards for meat and poultry set by USDA-FSIS must be consistent with those promulgated under FFDCA.³⁷

In November 2018, USDA-FSIS and HHS-FDA issued a statement announcing that they would regulate cell-based meat jointly, leveraging differences in agency specializations and expertise to oversee the novel, multi-phase production process.³⁸ In the announcement, and as elaborated upon in a subsequent Formal Agreement (“Formal Agreement”), the agencies make clear that cell-based meat and poultry products are meat and poultry products within the definitions set forth in the FMIA and the PPIA.³⁹ In these documents, the agencies affirm that existing statutory authority under the FMIA, the PPIA, and the FFDCA is sufficient to regulate cell-based products through the agreed-upon joint framework.⁴⁰ Under the Formal Agreement, HHS-FDA will leverage its expertise in cell-culture technology and living biosystems to oversee the initial phases of cell-based meat development for “USDA-amenable species,” including the cell collection, development, proliferation, and differentiation processes.⁴¹ At the time of harvest, jurisdiction will shift from HHS-FDA to USDA-FSIS, which will regulate the production and labeling of cell-based meats.⁴² Both HHS-FDA and USDA-FSIS will inspect cell-based meat production facilities, but HHS-FDA will be solely responsible for pre-harvest production and USDA-FSIS will be solely responsible for inspecting the final stages of production.⁴³ The Formal Agreement requires that establishments producing cell-based meat obtain a grant of inspection if the meat is intended for use as “human food required to bear the USDA mark of inspection.”⁴⁴ Further, USDA-FSIS must pre-approve all labels on cell-based meat, specifically requiring pre-

³¹ 70 Fed. Reg. 29214. *See also* 21 U.S.C. § 678 (meat); 21 U.S.C. § 467(e) (poultry).

³² *See* 21 U.S.C. § 678 (meat); 21 U.S.C. § 467(e) (poultry); USDA-FSIS, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS, at 13 (Aug. 2007), https://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES. *See also* Jones v. Rath Packaging Co., 430 U.S. 519 (1977) (U.S. Supreme Court decision upholding the FMIA preemption of state meat labeling law).

³³ 21 U.S.C. 301, *et seq.*

³⁴ 42 U.S.C. 201, *et seq.*

³⁵ 15 U.S.C. 1451 *et seq.*

³⁶ 21 U.S.C. § 607(c) (meat); 21 U.S.C. § 457(b) (poultry); USDA-FSIS, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS, *supra* note 32, at 10.

³⁷ *Id.*

³⁸ STATEMENT FROM USDA SECRETARY PERDUE AND FDA COMMISSIONER GOTTLIEB, *supra* note 3.

³⁹ *See id.*; FORMAL AGREEMENT, *supra* note 3.

⁴⁰ *Id.*

⁴¹ FORMAL AGREEMENT, *supra* note 3.

⁴² STATEMENT FROM USDA SECRETARY PERDUE AND FDA COMMISSIONER GOTTLIEB, *supra* note 3.

⁴³ FORMAL AGREEMENT, *supra* note 3, at 3.

⁴⁴ *Id.*

approval and verification under the Formal Agreement of labels on “human food products derived from the cultured cells of livestock and poultry.”⁴⁵

In June 2019, USDA-FSIS and HHS-FDA established three working groups to execute the Formal Agreement including a labeling working group, led by USDA-FSIS, which “focus[es] on developing joint principles for product labeling and claims.”⁴⁶ In September 2019, officials publicly announced that USDA-FSIS had initiated the process of drafting regulations for labeling of cell-based meats and a standard of identity.⁴⁷ In February 2020, USDA-FSIS and HHS-FDA signaled that the agencies expect cell-based meat product labeling to reflect variations in product characteristics and stated that discussions with the cell-based meat industry should begin soon.⁴⁸ Also in February 2020, USDA-FSIS stated that it intends to coordinate with HHS-FDA on “a public process to determine how [a cell-based meat product] can be labeled, what it should be named, what it can be named, what claims it can carry, etc.”⁴⁹ Most recently, in April 2020, the U.S. Government Accountability Office (“GAO”) published a report on the regulatory oversight of cell-based meat, which noted, among other things, that “USDA has committed to a public process, likely rulemaking, for the development of labeling requirements for cell-cultured meat and poultry.”⁵⁰ The GAO report also noted that regulators do not yet have access to specific information about final cell-based meat product compositions and processes.⁵¹

It is at this juncture that ALPC writes to urge USDA-FSIS to adopt a labeling approach that does not overly restrict speech and that respects First Amendment commercial speech protections. In its labeling approach, USDA-FSIS should not require new standards of identity and should not ban the use of common or usual meat or poultry terms or other product terms specified

⁴⁵ *Id.*

⁴⁶ U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-20-325, FOOD SAFETY: FDA AND USDA COULD STRENGTHEN EXISTING EFFORTS TO PREPARE FOR OVERSIGHT OF CELL-CULTURED MEAT 20 (April 2020) <https://www.gao.gov/products/GAO-20-325> [hereinafter GAO CELL-CULTURED MEAT REPORT].

⁴⁷ See Remarks by Rosalyn Murphy-Jenkins, *supra* note 5.

⁴⁸ Matthew Michael, Director of the Issuances Staff, USDA-FSIS, and Jeremiah Fasano, Ph.D., senior policy advisor, Office of Food Additive Safety’s Division of Science and Technology, Center for Food Safety and Applied Nutrition, U.S. FOOD & DRUG ADMIN., *Animal Cell-Culture Food Technology: A New Regulatory Frontier*, FOOD SAFETY MAG., Feb./Mar. 2020, at 48, <https://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2020/animal-cell-culture-food-technology-a-new-regulatory-frontier/> (“We expect that many characteristics of the products that can be produced by these processes and technologies will vary, such as the composition, nutritional content, shelf life, and functionality. We believe that many of these characteristics will need to be reflected through the labeling of these products, which may require careful evaluation and an iterative, data-driven dialogue with industry. Given these considerations, we also believe that these discussions with industry should begin soon to prevent unnecessary delays once companies are ready to bring products to market.”).

⁴⁹ Matthew Michael, Director of the Issuances Staff, *Actualities: USDA to Work with FDA on Labeling of Cell Cultured Foods*, USDA-FSIS (Feb. 24, 2020), <https://www.usda.gov/media/radio/daily-newsline/2020-02-24/actualities-usda-work-fda-labeling-cell-cultured-foods>.

⁵⁰ GAO CELL-CULTURED MEAT REPORT, *supra* note 46, at 17.

⁵¹ *Id.* at 11 (“The technology to produce cell-cultured meat at a commercial scale is still in development, and information about the methods to be used for commercial production and the composition of the final product are not yet known. In the continuum of moving a technology from innovation to commercialization, cell-cultured meat firms are in the middle stage of building and testing their prototypes. Consequently, they have not finalized aspects of the technology and eventual commercial production methods to be used or the composition of the final product. As a result, certain information is not yet available to stakeholders—including cell-cultured meat firms themselves, regulators, and the public—about specific aspects of the technology and commercial production methods that will be used, such as the composition of the growth medium and of the final products.”).

in standards of identity. Instead, USDA-FSIS should compel process-based disclosures or qualifiers on cell-based meat product labels only on a case-by-case basis when necessary to protect consumers from an increased food safety risk or material compositional difference, and USDA-FSIS should permit the use of credence claims. Further, USDA-FSIS should wait until it has a better understanding of the compositional and safety characteristics of finished cell-based meat products, and until it has had the opportunity to review proposed labels, before establishing speech restrictions that raise constitutional questions. By delaying the establishment of restrictive labeling requirements, USDA-FSIS will be able to assess whether, or to what extent, such speech restrictions actually are necessary in order to protect consumers from being misled and thus will be better able to ensure that such labeling requirements remain constitutional.

III. Cell-Based Meat Labels Are Commercial Speech Protected by the First Amendment

The First Amendment to the U.S. Constitution guarantees protections for commercial speech. Overly restrictive labeling regulations for cell-based meat products could violate this constitutional protection. To determine permissible restrictions on commercial speech under the First Amendment, courts have developed an extensive jurisprudence. The Supreme Court has held that commercial speech is protected under the First Amendment as long as it is not false, deceptive, misleading, or encouraging of illegal transactions.⁵² Package labels are a form of commercial speech because they do “no more than propose a commercial transaction.”⁵³ Labels for cell-based meat products thus will be protected as commercial speech under the First Amendment unless they are inherently false, deceptive, or misleading, or they propose illegal activity.

Constitutional protections on commercial speech, however, are not without limits. To evaluate the constitutionality of commercial speech restrictions, courts apply the four-prong test set out in *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*.⁵⁴ Under that test, if commercial speech is not inherently false, deceptive, or misleading, and it concerns legal activities, the government must assert a substantial interest to infringe upon that speech.⁵⁵ If the government successfully establishes a substantial interest, any regulations the government places on speech must “directly advance[] the governmental interest asserted” and must not be

⁵² See *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770–71 (1976); *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011) (holding that pharmaceutical marketing is protected commercial speech and subject to “heightened judicial scrutiny”).

⁵³ *Virginia State Board of Pharmacy*, 425 U.S. at 762. See also *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 478 (1995) (striking down a provision regulating beer labels as a violation of First Amendment commercial speech protections); *Sorrell v. IMS Health Inc.*, 564 U.S. at 557 (“Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment.”); *Zauderer v. Off. of Disc. Counsel of S. Ct. of Ohio*, 471 U.S. 626, 637 (1985) (quoting *Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447, 455–56 (1978)) (“Our commercial speech doctrine rests heavily on ‘the “common-sense” distinction between speech proposing a commercial transaction . . . and other varieties of speech”’); *Intl. Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 632 (6th Cir. 2010) (striking down a “regulation’s prophylactic ban on composition claims” on the labels of milk products as a violation of the First Amendment’s protections of commercial speech).

⁵⁴ *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980).

⁵⁵ *Id.*; see also *Zauderer*, 471 U.S. at 638 (“Commercial speech that is not false or deceptive and does not concern unlawful activities, however, may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest.”).

“more extensive than is necessary to serve that interest.”⁵⁶ Should a regulation fail any prong of this test, a court will find it unconstitutional.

The first prong of *Central Hudson* tests the truth and accuracy of commercial speech.⁵⁷ The Constitution offers no protection for “commercial speech that is false, deceptive, or misleading or that proposes an illegal transaction,” but truthful, non-deceptive speech that concerns only legal activities is protected commercial speech.⁵⁸ Commercial speech that is only “potentially misleading” but not “inherently misleading” is protected under the First Amendment and the constitutional analysis of restrictions upon it must proceed to the remaining three *Central Hudson* prongs.⁵⁹ Absent further information regarding the composition and safety of finished cell-based meat products as well as proposed labeling for such products, it is too soon to determine whether producers will attempt to label their products in ways that courts might find inherently false, deceptive, or misleading.⁶⁰ As such, it is premature for USDA-FSIS to promulgate regulations that ban or restrict the use of common or usual meat terms in anticipation that labels *might* be misleading in the future. Such prophylactic bans or restrictions are likely unconstitutional.⁶¹ USDA-FSIS should evaluate whether there is in fact a need to promulgate restrictive regulations by first determining whether cell-based meat products are materially different from their conventional slaughter-based meat counterparts and then reviewing actual product labels. As outlined in the Formal Agreement, HHS-FDA will share results of premarket consultation processes for cell-based meat products with USDA-FSIS, enabling both agencies to assess the composition and safety of such products.⁶² Moreover, under the Formal Agreement, USDA-FSIS will pre-approve each cell-based meat product label before it reaches the market and then verify

⁵⁶ Bd. of Trustees of State U. of New York v. Fox, 492 U.S. 469, 475 (1989) (quoting *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566); *see, e.g.*, *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (applying the *Central Hudson* test).

⁵⁷ *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566.

⁵⁸ *Zauderer*, 471 U.S. at 638 (citing *Friedman v. Rogers*, 440 U.S. 1 (1979); *Pittsburgh Press Co. v. Human Relations Comm’n*, 413 U.S. 376 (1973)).

⁵⁹ *See, e.g.*, *In re R. M. J.*, 455 U.S. 191, 203 (1982) (“States may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive.”); *Ibanez v. Fla. Dept. of Bus. and Prof. Reg., Bd. of Accountancy*, 512 U.S. 136, 146 (1994) (“[W]e cannot allow rote invocation of the words ‘potentially misleading’ to supplant the Board’s burden to ‘demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.’” (quoting *Edenfield v. Fane*, 507 U.S. 761, 771 (1993))); *Pearson v. Shalala*, 164 F.3d at 655 (finding that “health claims lacking ‘significant scientific agreement’ are not ‘inherently misleading’ and applying the remaining three *Central Hudson* prongs to ‘potentially misleading’ speech (emphasis in original)); *Alexander v. Cahill*, 598 F.3d 79, 89 (2d Cir. 2010) (“[T]he *Central Hudson* analysis applies to regulations of commercial speech that is only *potentially* misleading.” (emphasis in original)); *Grocery Mfrs. Ass’n v. Sorrell*, 102 F.Supp.3d 583, 639 (D. Vt. 2015) (“Speech that is shown to be only *potentially* misleading is protected by the First Amendment.” (citations omitted) (emphasis in original)).

⁶⁰ *See Intl. Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 637 (6th Cir. 2010) (finding that where “the extent of [a compositional] difference . . . is still very much an open question,” such compositional claims “are not inherently misleading” and determining that the remaining three factors of *Central Hudson* must still be applied). However, it should be noted that cell-based meat producers have an incentive to voluntarily distinguish their products from conventional meat on labels in order to capitalize on anticipated price premiums for their products.

⁶¹ *See Zauderer v. Off. of Disc. Counsel of S. Ct. of Ohio*, 471 U.S. 626, 649 (1985) (“[B]road prophylactic rules may not be so lightly justified if the protections afforded commercial speech are to retain their force. . . . Given the possibility of policing . . . on a case-by-case basis, the prophylactic approach taken . . . cannot stand.”); *Intl. Dairy Foods Ass’n v. Boggs*, 622 F.3d at 639 (“Rule’s prophylactic ban of composition claims such as ‘rbST free’ is more extensive than necessary to serve the State’s interest in preventing consumer deception.”).

⁶² FORMAL AGREEMENT, *supra* note 3, at 2–3.

with inspection—a process that gives the agency the opportunity to ensure the truthfulness and accuracy of every label.⁶³

Under the second prong of *Central Hudson*, the government must assert a substantial governmental interest to restrict or compel protected commercial speech.⁶⁴ In promulgating cell-based label regulations, USDA-FSIS might successfully assert its governmental interests in protecting consumer health and welfare, the purposes underlying the agency's statutory authority to regulate labels.⁶⁵ If, however, USDA-FSIS sought to restrict or compel speech in order to protect slaughter-based meat producers, courts likely would find such restrictions to be unconstitutional. The preservation of economic competitiveness is not a purpose under which the statutory authority for USDA-FSIS to regulate labels was enacted,⁶⁶ and the Supreme Court and other courts have held that producers do not have a constitutional right to be free from competition or competitive impact.⁶⁷ More specifically, in assessing the validity of regulations, courts do not give weight to the competitive effect of labels on certain meat producers.⁶⁸ In other words, meat producers “have no right to be free from competition” under the FMIA.⁶⁹ As a result, the government is unlikely to succeed in advancing a claim that protecting the economic competitiveness of the existing slaughter-based meat industry is a substantial interest, given that such protection is neither a constitutional right nor within the purposes underlying the labeling authority of USDA-FSIS. Further, as the federal government has recognized, “consumer interest alone does not provide a sufficient basis to require labeling disclos[ures]” and “[a]bsent a sufficient basis to require such labeling, the agency cannot compel food manufacturers to label their foods.”⁷⁰

Under the third prong of *Central Hudson*, any regulation restricting or compelling protected commercial speech must advance the substantial interest that the government asserts.⁷¹ The interests of USDA-FSIS in protecting consumer health and welfare are unlikely to be

⁶³ *Id.* at 3.

⁶⁴ *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980).

⁶⁵ 21 U.S.C. § 602 (“It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.”).

⁶⁶ *Id.*

⁶⁷ *See, e.g., Tennessee Elec. Power Co. v. Tennessee Val. Auth.*, 306 U.S. 118, 139 (1939) (“The franchise to exist as a corporation . . . creates no right to be free of competition, and affords the corporation no legal cause of complaint by reason of the state's subsequently authorizing another to enter and operate in the same field.”); *Grain & Feed, Inc. v. Bergland*, 602 F.2d 929, 933 (10th Cir. 1979) *cert. denied*, 444 U.S. 1073 (1980) (“nor would the competitive impact be a violation of plaintiff's constitutional rights”); *Westport Taxi Serv., Inc. v. Adams*, 571 F.2d 697, 700 n.3 (2d Cir.), *cert. denied*, 439 U.S. 829 (1978) (“It is well established that there is no right to be free from governmental competition.”).

⁶⁸ *See, e.g., Nat'l Pork Producers Council v. Bergland*, 631 F.2d 1353, 1361 (8th Cir. 1980) (“[T]he competitive effect [of nitrate-free labels] on the producers of nitrate and nitrite-preserved products is of no consequence.”).

⁶⁹ *Id.*

⁷⁰ U.S. FOOD & DRUG ADMIN. RESPONSE TO CITIZEN PETITION FILED BY CENTER FOR FOOD SAFETY, Docket No. FDA-2011-P-0723, at 2 (Nov. 19, 2015). *See also Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 73–74 (2d Cir. 1996) (“We are aware of no case in which consumer interest alone was sufficient to justify requiring a product's manufacturers to publish the functional equivalent of a warning about a production method that has no discernable impact on a final product.” (citing *Ibanez v. Fla. Dept. of Bus. and Prof. Reg., Bd. of Accountancy*, 512 U.S. 136, 145 (1994)); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 n.6 (2d Cir. 2001) (“Although we applied the *Central Hudson* test in [*Int'l Dairy Foods Ass'n v. Amestoy*] . . . our decision was expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of ‘consumer curiosity.’”).

⁷¹ *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980).

advanced by restricting truthful, non-misleading cell-based meat labels that pass the first prong as protected commercial speech and that are required to obtain pre-approval by USDA-FSIS.⁷² No unique substantial interest in protecting health and welfare will be advanced by restricting or compelling speech on cell-based meat products that do not materially differ in composition or food safety risk from slaughter-based meat products.⁷³ Accordingly, USDA-FSIS should only require qualifying language or disclosures on cell-based meat labels when doing so will advance the government's interest in consumer health and welfare, for example, when cell-based products have increased food safety risks or differ materially in composition from their slaughter-based counterparts.

Under the fourth prong of *Central Hudson*, if the government seeks to restrict truthful and not inherently misleading commercial speech, it must use the least restrictive means necessary to achieve the substantial interest it advances.⁷⁴ A ban on the use of certain terms is a highly restrictive form of commercial speech regulation.⁷⁵ Indeed, if USDA-FSIS were to ban the use of certain terms or compel the use of disclosures or qualifying terms that imply inferiority of cell-based meat products, consumers actually could be misled if those products conform to their expectations for the slaughter-based equivalents.⁷⁶ For instance, consumers with allergies or other

⁷² See, e.g., *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) ("Truthful advertising related to lawful activities is entitled to the protections of the First Amendment.") (quoting *In re R.M.J.*, 455 U.S. 191, 203 (1982)); *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 639 (6th Cir. 2010) (finding that a prophylactic ban on compositional claims "does not directly advance the State's interest"); *Grocery Mrfs. Ass'n v. Sorrell*, 102 F.Supp.3d 583, 639–41 (D. Vt. 2015) (finding that a restriction on the use of the undefined term "natural" by some commercial speakers, but not all, did not "directly and materially advance[] the government interest asserted"); *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645, 652 (S.D. Ohio 1989) ("Absolute prohibition against the use of the word 'butter,' in advertising, and in the listing of ingredients or anywhere else on the label, does not directly advance the state interest involved").

⁷³ See, e.g., *U.S. v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar*, 265 U.S. 438, 445 (1924) ("When considered independently of the product, the method of manufacture is not material. The [A]ct requires no disclosure concerning it."); *Bad Frog Brewery, Inc. v. New York State Liquor Auth.*, 134 F.3d 87, 100 (2d Cir. 1998) ("[A] state must demonstrate that its commercial speech limitation is part of a substantial effort to advance a valid state interest, not merely the removal of a few grains of offensive sand from a beach of vulgarity."); *Intl. Dairy Foods Ass'n v. Amestoy*, 92 F.3d at 73 (where "neither consumers nor scientists can distinguish rBST-derived milk from milk produced by an untreated cow" and there is "no scientific evidence from which an objective observer could conclude that rBST has any impact at all on dairy products," the government could not justify a mandatory labeling disclosure on the basis of "real" harms (citing *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993))); 75 Fed. Reg. 52602 (Aug. 26, 2010) ("FDA cannot require additional labeling about production methods unless it is necessary to ensure that the labeling is not false or misleading . . . Another way of stating this point is that FDA cannot require labeling based on differences in the production process if the resulting products are not materially different due solely to the production process.").

⁷⁴ *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 564.

⁷⁵ *Zauderer v. Off. of Disc. Counsel of S. Ct. of Ohio*, 471 U.S. 626, 649 (1985) ("We are not persuaded that identifying deceptive or manipulative uses of visual media in advertising is so intrinsically burdensome that the State is entitled to forgo that task in favor of the more convenient but far more restrictive alternative of a blanket ban on the use of illustrations.").

⁷⁶ See, e.g., *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995) ("If . . . the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different. In the absence of evidence of a material difference . . . , the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act."); *Alliance for Bio-integrity v. Shalala*, 116 F. Supp. 2d 166, 179 (D.D.C. 2000) ("[T]he determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling"); U.S. FOOD & DRUG ADMIN. RESPONSE TO CITIZEN PETITION FILED BY CENTER FOR FOOD SAFETY, *supra* note 70, at 17 ("[I]f a food product 'does not differ in any significant way from what it purports to be, then it would be misbranding to label the

dietary sensitivities may not be able to identify the presence of allergens or other foods they seek to avoid.⁷⁷ Further, even if USDA-FSIS could show that labeling restrictions would directly advance a substantial interest in consumer health or welfare, there are less restrictive means of promoting that interest than a ban on the use of common or usual meat and poultry terms or product names in standards of identity on cell-based meat labels.⁷⁸ For example, requiring factual label disclosures on finished products that have increased food safety risks or materially differ in composition is a less restrictive way to promote consumer health and welfare.⁷⁹

Accordingly, USDA-FSIS should not ban the use of common or usual meat and poultry terms or product names specified in standards of identity on cell-based meat product labels because such a ban is likely to be unconstitutional. Any labeling disclosures USDA-FSIS does require must be reasonably related to the agency's interest in protecting consumer health and welfare and must be no more restrictive than necessary to advance this interest.⁸⁰ Absent additional evidence regarding the safety and composition of finished cell-based meat products, as well as details of the actual proposed labels for such products, USDA-FSIS will not have sufficient information to determine which labeling restrictions, if any, are no more restrictive than necessary to advance its asserted interests. Instead, USDA-FSIS should wait until it has more information about the composition and safety of finished cell-based meat products and an opportunity to review proposed labels before establishing speech restrictions that raise constitutional questions. By delaying the establishment of restrictive labeling requirements, USDA-FSIS will be able to assess whether, or to what extent, such speech restrictions are actually necessary in order to protect consumers from

product as different,' particularly based on unsubstantiated and speculative risks." (quoting *Stauber*, 895 F. Supp. at 1193)); USDA-FSIS, LABELING TURKEY HAM PRODUCTS, POLICY MEMORANDUM 059 (Mar. 29, 1983), https://www.fsis.usda.gov/wps/wcm/connect/92485d36-be7f-451b-9153-7a921b13dc72/Policy_Memos_101818.pdf?MOD=AJPERES (noting that where "products conform to public expectations, consumers may be confused or misled by terminology which seems to connote an inferior product").

⁷⁷ See, e.g., *Lever Bros. Co.*, 712 F. Supp. at 652 ("In the case of [the product at issue], which is half butter, the absolute ban on the use of the word 'butter' . . . would not only fail to serve [the state's] interest in ensuring public recognition of the contents of the food item, but would actually frustrate that interest. [T]he public could not be informed, either through the [product] label or advertising, that plaintiff's product contained butter. Indeed, such a ban might have severe implications for those consumers who [have a health-related dietary restriction].").

⁷⁸ *Zauderer*, 471 U.S. at 649 ("[B]road prophylactic rules may not be so lightly justified if the protections afforded commercial speech are to retain their force. . . . Given the possibility of policing . . . on a case-by-case basis, the prophylactic approach taken . . . cannot stand.").

⁷⁹ See *id.* at 651 (stating that "purely factual and uncontroversial" mandatory "disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech"); *Buckley v. Valeo*, 424 U.S. 1 (1976) (upholding mandatory campaign contribution disclosure requirement); *Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999) ("It is clear, then, that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means."); *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228, 1240 (11th Cir. 2017) ("[T]he State. was unable to show that forbidding the Creamery from using the term 'skim milk' was reasonable, and not more extensive than necessary to serve its interest. It 'disregard[s] far less restrictive and more precise means'—for example, allowing skim milk to be called what it is and merely requiring a disclosure that it lacks vitamin A." (quoting *Bd. of Trustees of State U. of New York v. Fox*, 492 U.S. 469, 479 (1989))); *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645, 652 (S.D. Ohio 1989) ("[The state's] interest would be better served by a more limited restriction [than an absolute ban] on commercial speech which would ensure that the word 'butter' is not used in a false or misleading manner and that the public is accurately informed about the precise butter content of the product."). For further discussion of the application of *Zauderer* by lower courts, see Nigel Barrella, *First Amendment Limits on Compulsory Labeling*, 71 FOOD & DRUG L. J. 519, 526 (2016).

⁸⁰ *Zauderer*, 471 U.S. at 651.

being misled. USDA-FSIS should then make determinations on a case-by-case basis and require factual disclosures or qualifying language only on the labels of cell-based products that present increased food safety risks or differ materially in final composition from slaughter-based equivalents.

In evaluating First Amendment protections for commercial speech on cell-based product labels, there are two other important considerations that USDA-FSIS should acknowledge. First, courts may review content-based restrictions on commercial speech with heightened scrutiny.⁸¹ As the Supreme Court has held, “speech regulation is content based if a law applies to particular speech because of the topic discussed or the idea or message expressed.”⁸² A court may find that if USDA-FSIS promulgates regulations restricting or compelling certain terms on labels of cell-based meat products (as some states have prospectively done) but not on labels of slaughter-based meat products, those regulations are content-based. Further, even a facially neutral law is considered content-based if it “cannot be justified without reference to the content of the regulated speech, or [was] adopted by the government because of disagreement with the message [the speech] conveys.”⁸³ Should USDA-FSIS impose specific labeling regulations unique to cell-based meat products, a court may find those regulations to be content-based if they refer and apply only to cell-based meat. On either basis, if the reviewing court were to apply strict scrutiny, restrictive labeling regulations would be significantly less likely to survive judicial review and more likely to be found unconstitutional.⁸⁴ Second, it is worth noting that, in reviewing regulations restricting commercial speech, courts will construe regulations and their authorizing statutes (including the FMIA and the PPIA) as narrowly as possible in order to avoid a constitutional question.⁸⁵ Accordingly, a court may interpret narrowly a regulation banning the use of certain terms on cell-based meat labels.

IV. Proposed Labeling Regime

In light of the First Amendment protections for cell-based meat labels that are not inherently misleading, USDA-FSIS should adopt a labeling approach that does not overly restrict speech. First, USDA-FSIS should not establish new standards of identity. Second, USDA-FSIS should not ban the use of common or usual meat and poultry terms, or product names specified in standards of identity, by cell-based meat producers. Third, USDA-FSIS should wait until it has

⁸¹ While the doctrine is clearer for content-based noncommercial speech, in at least one recent instance the Supreme Court applied strict scrutiny to content-based speech that is arguably commercial speech. *See Reed v. Town of Gilbert*, Ariz., 135 S. Ct. 2218, 2235 (2015) (Breyer, J., concurring) (citing *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 581–82 (2011) (Breyer, J., dissenting) (“[T]he Court has applied the heightened ‘strict scrutiny’ standard even in cases where the less stringent ‘commercial speech’ standard was appropriate.”)). *But see Central Hudson Gas & Elec. Corp. v. Public Service Com’n of N. Y.*, 447 U.S. 557, 562–563 (1980) (stating that “The Constitution . . . accords a lesser protection to commercial speech than to other constitutionally guaranteed expression” and applying intermediate scrutiny to review of commercial speech).

⁸² *Reed v. Town of Gilbert*, 135 S.Ct. at 2227 (citing *Sorrell v. IMS Health Inc.*, 564 U.S. at 564–65).

⁸³ *Id.* (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989)) (internal quotations omitted).

⁸⁴ Strict scrutiny is an exacting standard of review that is more challenging than the intermediate standard applied under *Central Hudson*. *See, e.g., id.* at 2222 (“Because content-based laws target speech based on its communicative content, they are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.”); *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 623 (1995) (labeling the *Central Hudson* test as intermediate scrutiny).

⁸⁵ *See, e.g., Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Eng’rs*, 531 U.S. 159, 172–73 (2001).

more information about compositional and safety differences to determine what labeling requirements are no more restrictive than necessary, and it should only compel process-based qualifiers or disclosures on a case-by-case basis when needed to protect consumers from an increased food safety risk or material difference in final product composition compared to the slaughter-based equivalent. USDA-FSIS should allow producers to differentiate and explain cell-based meat products by communicating to consumers what each product is and how to consume it, including by reference to common or usual terms, so long as any representations made are not misleading. Fourth, cell-based meat producers should be allowed to make claims such as “plastic-free” and “nitrate-free” so long as they can provide sufficient documentation for accurate substantiation of those claims.

A. USDA-FSIS should not establish new standards of identity

The implementation of a labeling approach similar to that proposed here would not require USDA-FSIS to promulgate new standards of identity. Standards of identity specify recipes or compositional parameters that a product must meet in order to qualify to use a standardized term.⁸⁶ Because cell-based meat products are expected to be materially the same in composition as their slaughter-based counterparts and present lower risks in many ways, new standards of identity are not required. Rather, if cell-based meat products are compositionally the same as their slaughter-based equivalents and can conform with existing standards of identity, those products can be labeled with the respective standardized terms without being “misbranded.”⁸⁷

The technology and science of cell-based meat products continues to evolve rapidly. Not only would new standards of identity be time-consuming and resource-intensive to establish, but standards of identity for cell-based meat products would inhibit innovation if they were not flexible enough to accommodate technological changes or as-yet-unforeseeable products. This past year, HHS-FDA, which shares jurisdiction over establishing meat and poultry product standards of identity,⁸⁸ solicited public input on ways to systematically modernize standards of identity in order to “promote industry innovation and provide flexibility to encourage manufacturers to produce healthier foods,”⁸⁹ implicitly recognizing the rigidity of the current standards of identity structure. The standards of identity modernization process started decades earlier when, in 1995, USDA-FSIS and HHS-FDA began considering how to update their standards of identity in order “to grant the flexibility necessary for timely development and marketing of products that meet consumer needs, while at the same time providing consumer protection.”⁹⁰ As USDA-FSIS recognized at

⁸⁶ See U.S. FOOD & DRUG ADMIN., FOOD STANDARDS UNDER THE 1938 FOOD, DRUG, AND COSMETIC ACT (Jan. 18, 2018), <https://www.fda.gov/about-fda/histories-product-regulation/food-standards-under-1938-food-drug-and-cosmetic-act-bread-and-jam>.

⁸⁷ See 21 U.S.C. § 601(n). If a standard of identity is already established, a meat product is not misbranded if “(A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

⁸⁸ 21 U.S.C. § 607(c) (meat); 21 U.S.C. § 457(b) (poultry); USDA-FSIS, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS, *supra* note 32, at 10.

⁸⁹ FDA Announces Public Meeting to Discuss Modernizing Food Standards of Identity, U.S. FOOD & DRUG ADMIN. (Aug. 28, 2019), <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-public-meeting-discuss-modernizing-food-standards-identity>.

⁹⁰ 70 Fed. Reg. 29217 (May 20, 2005) (describing the 1995 USDA-FSIS and HHS-FDA advance notices of proposed rulemaking on food standards).

that time, “existing food standards also may prevent the food industry from producing products that have lower amounts of constituents associated with negative health implications, such as fat, saturated fat, cholesterol, and sodium.”⁹¹ Similarly, establishing new standards of identity for cell-based meat products under the existing framework will create delays, result in rigid requirements that will be impair future innovation, and reduce the ability of producers to create healthier, more sustainable, and more humane products. Furthermore, in 2005, USDA-FSIS and HHS-FDA jointly issued a proposal in which both agencies maintain that:

Establishing regulations that do not stifle innovations in food technology and allow for technological alternatives and advancements in food processing would improve manufacturing efficiency and lessen costs which may be passed on to the consumer. Improved technologies may additionally benefit product quality and diversity. Increased diversity in, and potentially lower costs of, food products in the marketplace that continue to meet consumer expectations would promote honesty and fair dealing in the interest of consumers and protect the public.⁹²

Therefore, the agencies proposed changes to:

[P]rovide that the food standard should permit maximum flexibility in the food technology used to prepare the standardized food, so long as that technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality, or safety of the food. In addition, these provisions would state that the food standard should provide for any suitable, alternative manufacturing process that accomplishes the desired effect and should describe ingredients as broadly and generically as feasible.⁹³

In order to promote this agency goal of maximizing food technology flexibility, to prevent significant and unnecessary delays, and to facilitate innovation, USDA-FSIS should not establish new standards of identity for cell-based meat products.

B. USDA-FSIS should not ban the use of common or usual meat and poultry terms or product names specified in standards of identity on cell-based meat labels

As discussed above, a ban on the use of common or usual meat and poultry terms on cell-based meat labels is likely unconstitutional. Further, under the Formal Agreement signed with HHS-FDA, USDA-FSIS recognizes its authority to regulate cell-based meat as “meat” and “poultry” within the FMIA and the PPIA and that producers of these products should be allowed to label them as such.⁹⁴ Permitting the use of common or usual meat and poultry terms and product names specified in standards of identity on products acknowledged as meat and poultry also aligns with current USDA-FSIS policy. When meat is produced using innovative technologies but remains materially the same in terms of risk and final composition, such as with advanced meat recovery systems, USDA-FSIS does not prohibit the use of common or usual

⁹¹ *Id.* (citing 61 Fed. Reg. 47453 (Sept. 9, 1996)).

⁹² *Id.* at 29222.

⁹³ *Id.*

⁹⁴ FORMAL AGREEMENT, *supra* note 3, at 1.

meat and poultry terms.⁹⁵ Labeling differentiation or disclosure also is not required on meat from cloned animals and their progeny.⁹⁶ Likewise, cell-based meat producers should be permitted to use common or usual meat and poultry terms on their product labels. Prohibiting them from doing so would be inconsistent with current USDA-FSIS policy and may violate the First Amendment.

As outlined in the Formal Agreement, HHS-FDA will conduct a pre-market safety consultation with cell-based meat producers and USDA-FSIS will pre-approve all cell-based meat product labels before they can be marketed to consumers and verified with inspections.⁹⁷ These pre-approval processes afford the agency an opportunity to ensure the truthfulness and accuracy of every label. Moreover, the pre-approval process allows for case-by-case assessments of necessary distinctions or restrictions, which are the type of commercial speech restrictions that the Supreme Court has approved of in the past.⁹⁸ This pre-approval process offers a less restrictive means for protecting consumers than a prophylactic ban on using common or usual meat and poultry terms on cell-based meat labels, and thus increases the likelihood that courts would find such a ban to be unconstitutional.

C. USDA-FSIS should require processing disclosures only where risk or composition differs materially

In certain circumstances, USDA-FSIS requires disclosure on labels of “meat” products created through innovative processes. Such disclosures are required where there is an increased food safety risk or when consumers are likely to be misled because the final product differs materially from their compositional expectations for its equivalent. For example, USDA-FSIS requires disclosure of the use of mechanical separation processes on pork and poultry products⁹⁹ and of mechanical tenderization processes on raw beef products¹⁰⁰ because those processes introduce heightened food safety risks. Similarly, when meat is produced using an advanced meat

⁹⁵ See, e.g., 9 C.F.R. § 318.24 (products produced using advanced meat recovery (AMR) do not have a unique disclosure requirement or standard of identity as long as certain process controls were used); Joe Fassler, *ABC News Called It “Pink Slime.” Now, USDA Says It Can Be Labeled “Ground Beef,”* THE COUNTER (Feb. 7, 2019) (“After reviewing BPI’s submission of a new product and new production process, FSIS determined that the product meets the regulatory definition of ground beef under the law in 9 CFR 319.15(a) and may be labeled accordingly”), <https://thecounter.org/bpi-pink-slime-ground-beef-usda-reclassified/>.

⁹⁶ See U.S. FOOD & DRUG ADMIN., ANIMAL CLONING AND FOOD SAFETY, <https://www.fda.gov/consumers/consumer-updates/animal-cloning-and-food-safety> (“Food labels do not have to state that food is from animal clones or their offspring. FDA has found no science-based reason to require labels to distinguish between products from clones and products from conventionally produced animals.”).

⁹⁷ FORMAL AGREEMENT, *supra* note 3, at 3.

⁹⁸ See *Zauderer v. Off. of Disc. Counsel of S. Ct. of Ohio*, 471 U.S. 626, 649 (1985) (“[B]road prophylactic rules may not be so lightly justified if the protections afforded commercial speech are to retain their force. . . . Given the possibility of policing . . . on a case-by-case basis, the prophylactic approach taken . . . cannot stand.”).

⁹⁹ USDA, MEAT AND POULTRY LABELING TERMS: MECHANICALLY SEPARATED MEAT & MECHANICALLY SEPARATED POULTRY, <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms/>.

¹⁰⁰ *Beef Retailers Now Labeling Mechanically Tenderized Beef*, USDA (Feb. 21, 2017), <https://www.usda.gov/media/blog/2016/05/20/beef-retailers-now-labeling-mechanically-tenderized-beef>.

recovery system process and varies compositionally, such as when its calcium content exceeds the specified limit, USDA-FSIS mandates disclosure in that product's ingredients statement.¹⁰¹

Where innovative processes used to produce meat do not result in material compositional or risk differences, USDA-FSIS does not require disclosure. For example, distinctive labeling or disclosure is not required for slaughter-based meat produced from cloned animals because HHS-FDA determined that cloned meat presents no heightened safety risk, a decision with which USDA-FSIS concurred.¹⁰² Other examples of products that are not subject to process-based disclosure requirements because they do not differ materially in composition or safety risk include certain products derived from advanced meat recovery systems using specified process controls and mechanically tenderized cooked beef products.¹⁰³ Accordingly, because it has recognized cell-based meat as "meat," USDA-FSIS should not compel the use of qualifiers or disclosures on cell-based meat product labels unless those products differ materially in final composition or risk from their analog slaughter-based meat counterparts. To determine whether material compositional or safety-based differences exist, USDA-FSIS will be able to draw from the information dossier collected by HHS-FDA during the pre-market safety consultation, as outlined in the Formal Agreement.¹⁰⁴ Using that information, together with actual labels for submitted for pre-approval, USDA-FSIS will be able to determine on a case-by-case basis whether increased food safety risks or material compositional differences exist in cell-based meat products compared to their slaughter-based equivalents, and whether appropriate disclosures, such as in ingredients

¹⁰¹ 59 Fed. Reg. 62551, 62554 (Dec. 6, 1994); USDA, MEAT AND POULTRY LABELING TERMS: "MEAT" DERIVED BY ADVANCED MEAT/BONE SEPARATION AND MEAT RECOVERY SYSTEMS, <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms/>.

¹⁰² U.S. FOOD & DRUG ADMIN., ANIMAL CLONING AND FOOD SAFETY, *supra* note 96 (finding no science-based reason for labeling of cloned meat); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #179, USE OF ANIMAL CLONES AND CLONE PROGENY FOR HUMAN FOOD AND ANIMAL FEED (Jan. 15, 2008) ("[FDA] did not identify any unique risks for human food from cattle, swine, or goat clones, and concluded that . . . food from cattle, swine, and goat clones is as safe to eat as that from their more conventionally-bred counterparts."); *FDA's Final Risk Assessment, Management Plan and Industry Guidance as Animal Clones and their Progeny*, Press Release No. 0011.08, USDA (Jan. 15, 2008) ("Because FDA has determined that food from clones of specified species and the offspring of clones from any species traditionally consumed as food are safe and no different from conventionally bred animals, there is no basis to require labeling of food products from clones or their progeny."); Statement by Bruce Knight, Under Secretary for Marketing and Regulatory Programs on FDA Risk Assessment on Animal Clones (Jan. 15, 2008) ("USDA fully supports and agrees with FDA's final assessment that meat and milk from cattle, swine and goat clones pose no safety concerns, and these products are no different than food from traditionally bred animals.").

¹⁰³ See, e.g., 9 C.F.R. § 318.24 (products produced using advanced meat recovery (AMR) do not have a process-based disclosure requirement as long as certain process controls were used); 78 Fed. Reg. 34593 (no processed-based disclosure is required for mechanically tenderized beef products that "are fully cooked in an official establishment because such products do not pose the same pathogen hazard as the raw or partially cooked products. Further, consumers can recognize that a product has been cooked"). For further discussion of process-based labeling disclosures, see Memphis Meats, *Memphis Meats Response to Petition to Establish Beef and Meat Labeling Requirements: To Exclude Product Not Derived Directly from Animals Raised and Slaughtered from the Definition of "Beef" and "Meat,"* Petition 18-01, Docket ID: FSIS-2018-0016 (May 2, 2018), <https://www.regulations.gov/document?D=FSIS-2018-0016-0047>.

¹⁰⁴ FORMAL AGREEMENT, *supra* note 3, at 2.

statements, are necessary.¹⁰⁵ Mandating differentiation or disclosures on product labels only where there are actual material differences in final composition or in food safety risk is more likely to withstand constitutional scrutiny than more restrictive approaches, and doing so would be consistent with existing USDA-FSIS policies for requiring process-based disclosures.

Beyond the considerations already discussed, a labeling scheme that permits the use of common or usual meat and poultry terms and only requires disclosure for a risk or composition-based difference would promote innovation in American agricultural products. It also would be aligned with the directive from the Administration's Executive Order to streamline regulation.¹⁰⁶ Finally, it would be consistent with longstanding agency biotechnology policy not to mandate disclosure of process-based differences where the final products do not differ materially from their traditional counterparts.¹⁰⁷ To require otherwise for cell-based meat, a type of biotechnology product, likely would be deemed "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" under the Administrative Procedure Act.¹⁰⁸

D. USDA-FSIS should allow producers to make credence claims

Cell-based meat producers should be permitted to make claims such as "plastic-free" and "nitrate-free" and other credence claims so long as they can sufficiently substantiate those claims. If it is not inherently false, deceptive, or misleading, or promoting illegal activity, speech on product labels, including claims, is a form of protected commercial speech and restrictions on it are subject to at least the *Central Hudson* test.¹⁰⁹ Courts have upheld regulations permitting

¹⁰⁵ This approach is similar to the case-by-case determinations of material differences in composition or safety that USDA-FSIS makes for other processed-based technologies such as advanced meat recovery (*see* 9 C.F.R. § 318.24) and mechanically tenderized beef (*see* 78 Fed. Reg. 34593).

¹⁰⁶ Exec. Order No. 13874, 84 FR 27899, Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products, Land & Agriculture (June 11, 2019).

¹⁰⁷ *See, e.g.*, U.S. FOOD & DRUG ADMIN., ANIMAL CLONING AND FOOD SAFETY, *supra* note 96 (finding no science-based reason for labeling of cloned meat). It was longstanding HHS-FDA policy to not require disclosure of "bioengineered" foods. *See, e.g.*, 57 Fed. Reg. 22984, 22991 (May 29, 1992) ("FDA has not considered [bioengineering techniques] to be material information The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or . . . present any different or greater safety concern For this reason, the agency does not believe that the method of development of a new plant variety . . . is normally material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labeling for the food."); 75 Fed. Reg. 52602 (Aug. 26, 2010) ("FDA cannot require additional labeling about production methods unless it is necessary to ensure that the labeling is not false or misleading Another way of stating this point is that FDA cannot require labeling based on differences in the production process if the resulting products are not materially different due solely to the production process."); U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE, VOLUNTARY LABELING INDICATING WHETHER FOOD HAS OR HAS NOT BEEN DERIVED FROM GENETICALLY ENGINEERED ATLANTIC SALMON 7 (Revised Mar. 2019) (not requiring a special label disclosure or a new standard of identity for genetically engineered salmon because it found that "food derived from [the salmon] is as safe and nutritious as food from other farm-raised Atlantic salmon."); U.S. FOOD & DRUG ADMIN. RESPONSE TO CITIZEN PETITION FILED BY CENTER FOR FOOD SAFETY, *supra* note 70, at 2 ("[W]ithout a finding of materiality, under the FD&C Act FDA cannot require that all foods derived from [genetically engineered] plants, as a class, be labeled as having been genetically engineered The FD&C Act plainly does not require disclosure of the method of production without regard to its effect on the product."). Since the President signed the National Bioengineered Food Disclosure Standard into law in 2016, however, producers must disclose the presence of "bioengineered" ingredients in products used for human consumption. 7 USCA § 1639 et seq.

¹⁰⁸ *See* 5 U.S.C. § 706(2)(A).

¹⁰⁹ Discussed in more depth *supra*.

absence claims on package labels, even where they might create competitive pressure on other producers.¹¹⁰ In evaluating such absence claims, courts do not consider potential competitive harm.¹¹¹ Documentation requirements should be consistent with current USDA-FSIS policy for applicable or similar claims, such as “negative claims.”¹¹² Consumers seek out new products for many reasons, including to avoid allergens or other unhealthful substances that may currently be found in slaughter-based animal products. Such consumers should be able to identify products that meet their needs. Permitting companies to make credence claims, so long as they are able to substantiate them, on cell-based meat product labels will improve transparency and consumer choice.

V. Conclusion

The Harvard Law School Animal Law & Policy Clinic thanks USDA-FSIS for considering the recommendations in this letter. As outlined above, ALPC urges USDA-FSIS to adopt a labeling approach for cell-based meat and poultry products that does not overly restrict speech and respects the First Amendment. In its labeling approach, USDA-FSIS should not establish new standards of identity and should not ban the use of common or usual meat and poultry terms or product names specified in existing standards of identity. Instead, USDA-FSIS should compel disclosures or qualifiers on cell-based meat labels only when doing so is necessary to protect consumers from an increased food safety risk or material compositional difference and should allow producers to use credence claims. Before requiring disclosures or qualifiers, USDA-FSIS should wait until it has had the opportunity to determine the composition and safety of finished cell-based meat products, to review actual proposed labels, and then to assess what, if any, specific labeling requirements are essential on a case-by-case basis to protect consumers from being misled. As the agency drafts its proposed cell-based meat labeling rules, ALPC respectfully requests that USDA-FSIS continue to coordinate closely with HHS-FDA.

In conclusion, ALPC urges USDA-FSIS to protect consumers without suppressing American innovation, to ensure consistency with the cell-based seafood labeling approach that HHS-FDA adopts, and to offer certainty to producers and states. Above all, ALPC encourages

¹¹⁰ See, e.g., *Nat’l Pork Producers Council v. Bergland*, 631 F.2d 1353, 1355 (8th Cir. 1980) (upholding regulation that permits “nitrate and nitrite-free meat products to be sold under product names traditionally reserved for foods containing these compounds”).

¹¹¹ See, e.g., *id.* at 1361 (citing *Hiatt Grain & Feed, Inc. v. Bergland*, 602 F.2d 929, 933 (10th Cir. 1979), *cert. denied*, 444 U.S. 1073 (1980); *Westport Taxi Serv., Inc. v. Adams*, 571 F.2d 697, 700 n.3 (2d Cir. 1978), *cert. denied*, 439 U.S. 829 (1978) (“[T]he producers of nitrate and nitrite-preserved products have no right to be free from competition.”)).

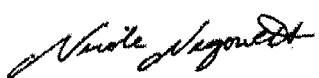
¹¹² See, e.g., USDA, LABELING GUIDELINE ON DOCUMENTATION NEEDED TO SUBSTANTIATE ANIMAL RAISING CLAIMS FOR LABEL SUBMISSIONS (Dec. 2019), <https://www.fsis.usda.gov/wps/wcm/connect/6fe3cd56-6809-4239-b7a2-bccb82a30588/RaisingClaims.pdf?MOD=AJPERES>; USDA, LABELING GUIDELINE ON STATEMENTS THAT BIOENGINEERED OR GENETICALLY-MODIFIED INGREDIENTS OR ANIMAL FEED WERE NOT USED IN MEAT, POULTRY, OR EGG PRODUCTS (Dec. 2019), <https://www.fsis.usda.gov/wps/wcm/connect/547972e6-cd56-4f0a-a5d5-d066ac12651b/labeling-guideline-bioengineered.pdf?MOD=AJPERES>; USDA, NEGATIVE INGREDIENT LABELING, POLICY MEMORANDUM 019B (Aug. 18, 1994), https://www.fsis.usda.gov/wps/wcm/connect/92485d36-be7f-451b-9153-7a921b13dc72/Policy_Memos_101818.pdf?MOD=AJPERES.

USDA-FSIS to “Do right and feed everyone”¹¹³ by regulating cell-based meat products in a fair, common-sense, and constitutional way.

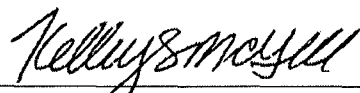
Sincerely,



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¹¹³ Remarks by USDA Secretary Perdue, *supra* note 2 (“Do right and feed everyone” is the new motto of the USDA).