



December 2, 2021

Docket No. FSIS-2020-0036

Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service
1400 Independence Avenue SW, Mailstop 3758, Room 6065
Washington, DC 20250-3700

Re: Docket No. FSIS–2020–0036; Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells—Comments of Harvard Law School Animal Law & Policy Clinic and Food Law and Policy Clinic

The Harvard Law School Animal Law & Policy Clinic and Harvard Food Law and Policy Clinic write to respectfully urge the U.S. Department of Agriculture’s Food Safety and Inspection Service (“USDA-FSIS”) to adopt a labeling approach for meat or poultry products comprised of or containing cultured animal cells that does not restrict speech, respects the First Amendment, and fosters consumer choice and technological innovation. Our position is largely unchanged from what we outlined in our June 2020 petition to the Commissioner;¹ we elaborate below on certain elements of our stance in response to the questions posed by this Advanced Notice of Proposed Rulemaking. 86 Fed. Reg. 49491 (Sept. 3, 2021).

The Harvard Animal Law & Policy Clinic (“ALPC”) undertakes work in 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 the welfare and lives of animals.

The Food Law and Policy Clinic (“FLPC”) serves partner organizations and communities in the U.S. and around the world by providing guidance on cutting-edge food system issues, while engaging law students in the practice of food law and policy. FLPC is committed to advancing a cross-sector, multi-disciplinary and inclusive approach to its work, building partnerships with academic institutions, government agencies, non-profit organizations, private sector actors, and civil society with expertise in public health, the environment, and the economy. FLPC’s work focuses on increasing access to healthy foods, supporting sustainable and equitable food production, reducing waste of healthy, wholesome food, and promoting community-led food system change.

¹ Petition 20-03 Submitted by Harvard Law School Animal Law & Policy Clinic, June 9, 2020, Exhibit A.

The joint position of both ALPC and FLPC is that meat or poultry products comprised of or containing cultured animal cells” (hereinafter referred to collectively as “cultivated meat and poultry products”) are important innovations in food production with tremendous potential to positively impact animals, human health, and environmental sustainability—while also creating an entirely new domestic food industry within the United States. Our response to the questions posed in the Federal Register Notice are detailed below. In support of these Comments, we also submit Exhibits A – P. In addition, we rely on various cited materials that are available electronically and hereby incorporate those materials by reference. Should the USDA-FSIS need downloaded copies of any of those materials, please let us know so that we can provide them.

1. Should the product name of a meat or poultry product comprised of or containing cultured animal cells differentiate the product from slaughtered meat or poultry by informing consumers the product was made using animal cell culture technology? If yes, what criteria should the agency consider or use to differentiate the products? If no, why not?

At this time, USDA-FSIS should not impose restrictions for the labeling of cultivated meat and poultry products, and any such labeling guidelines should remain flexible as industry consensus develops around preferred nomenclature for such products. Mandating the use of specific terms or labeling practices for cultivated meat and poultry products would both cut against established USDA-FSIS labeling practices and raise significant First Amendment concerns—potentially deterring the marketing and purchase of such products unnecessarily.

Historically, USDA-FSIS has required disclosures only when food safety concerns or material product differences are present in a regulated product.² In the case of cultivated meat and poultry products, neither concern is applicable. Most, if not all, cultivated meat and poultry products will be identical in physical composition and function to their slaughter-based counterparts, and the production process for such products does not increase food safety risks, such as in the case of mechanically tenderized meat products, for example.³ In fact, cultivated meat and poultry products may be prone to significantly fewer food safety hazards.⁴ As USDA-FSIS's own guidance materials elucidate, many of the food safety risks associated with slaughtered meat come from the very nature of *slaughtering* a live animal—pathogens and physical hazards can be introduced into conventionally slaughtered meat products from the hide of the animal, its fecal matter, the method of slaughter and processing (i.e. mechanical hazards from bullet fragments or bacterial cross-contamination from scalding media for animal carcasses), and so forth.⁵ While cultivated meat and poultry production is not totally risk-free, industry practices require the product to be created in clean industrial environments with a near absence of opportunity for such types of

² 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/>.

³ “FSIS is amending the [Federal meat inspection] regulations because of scientific evidence that mechanically tenderized beef products need to be fully cooked in order to reduce the risk of pathogenic bacteria that may be transferred to the interior of the meat during mechanical tenderization.” *USDA-FSIS, Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products*, 80 Fed. Reg. 28,153 (May 18, 2015).

⁴ See generally Good Food Institute, Good Food Institute, *Food safety considerations for cultivated meat*, Exhibit B.

⁵ See generally, USDA-FSIS, *Meat and Poultry Hazards and Controls Guide* (March 2018), https://www.fsis.usda.gov/sites/default/files/import/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf.

contamination.⁶ Additionally, the government historically has declined to require disclosures when the product of a novel process is indistinguishable from a previously approved product. An illustrative example is USDA-FSIS's labeling approach to meat from *cloned* animals, which is not required to be labeled with additional disclosures (despite being reproduced and grown using novel genetic and reproductive technology) because the process results in an end product that is identical to conventionally bred livestock.⁷

In evaluating First Amendment protections for commercial speech on cell-based product labels, there are three important considerations that USDA-FSIS should acknowledge. First, courts review content-based restrictions on commercial speech with heightened scrutiny under a four-part test outlined in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). Courts now invoke the four-part *Central Hudson* test “when analyzing almost any commercial speech restriction, with very few exceptions.”⁸ Under the *Central Hudson* test, courts “test the constitutionality of laws burdening commercial speech” by considering:

- (1) whether the commercial speech at issue concerns unlawful activity or is misleading;
- (2) whether the governmental interest is substantial;
- (3) whether the challenged regulation directly advances the government's asserted interest; and
- (4) whether the regulation is no more extensive than necessary to further the government's interest.⁹

Provided that the speech is not false or inherently misleading, “[e]ach of these latter three inquiries must be answered in the affirmative for the regulation to be found constitutional.”¹⁰ Following this inquiry, if the reviewing court were to apply the *Central Hudson* test to potentially restrictive labeling regulations, such restrictions would be more likely to be found unconstitutional.¹¹

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.¹² Accordingly, a court may narrowly interpret a regulation banning the use of certain terms on labels of meat and poultry products derived from cultured animal cells and would be unlikely to uphold overly restrictive regulations.

Third, courts analyze *compelled* commercial speech—i.e., required *disclosures*—under *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985). Compelled speech

⁶ Mark J. Post et al., *Scientific, sustainability and regulatory challenges of cultured meat*, 1 *Nature Food* 403-15, 403, Exhibit C.

⁷ FDA, *Animal Cloning and Food Safety* (August 2018), <https://www.fda.gov/consumers/consumer-updates/animal-cloning-and-food-safety>.

⁸ Nigel Barrella, *First Amendment Limits on Compulsory Labeling*, 71 *Food and Drug L.J.* 519, 519 (2016), Exhibit D.

⁹ *Cent. Hudson*, 447 U.S. at 566.

¹⁰ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002).

¹¹ 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).

¹² *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).

receives the lower standard of rational basis scrutiny under *Zauderer*. Under *Zauderer*, the government may require commercial speakers to divulge “purely factual and uncontroversial information” about their products or services, so long as it is “reasonably related” to a substantial government interest and is neither “unjustified [n]or unduly burdensome.”¹³ A challenge to a compelled disclosure, like a government-mandated labeling requirement, is likely to be successful if the information is either “not factual” or else “controversial”—placing it outside of *Zauderer*’s scope and forcing it to be analyzed under the more stringent *Central Hudson* test.

However, if USDA-FSIS nevertheless decides to impose any labeling restrictions on cultivated meat and poultry products, USDA-FSIS should equally require that conventionally raised and slaughtered meat be labeled, accordingly, as “slaughtered meat” (or “slaughtered beef patty,” “slaughtered chicken nugget,” etc.), to allow consumers to distinguish clearly between the two types of meat and poultry products. Using the *process* by which meat and poultry products are created as the primary labeling criterion for both cultivated and slaughtered products would be a fair labeling solution that would allow consumers to identify which type of meat or poultry product they are purchasing, but would not overly burden just one class of product in a competitive marketplace.

If producers *voluntarily* label food products to indicate they are comprised of or contain cultured animal cells, USDA-FSIS should require those claims to be substantiated by evidence that the products in question do indeed originate from cultured animal cells rather than from slaughtered meat or poultry products. This is to ensure that consumers are not misled or deceived into purchasing products claiming to be comprised of substances they do not contain.¹⁴

2. **What term(s), if any, should be in the product name of a food comprised of or containing cultured animal cells to convey the nature or source of the food to consumers? (e.g., “cell cultured” or “cell cultivated.”)**
 - a. **How do these terms inform consumers of the nature or source of the product?**
 - b. **What are the benefits or costs to industry and consumers associated with these terms?**
 - c. **If meat or poultry products comprised of or containing cultured animal cells were to be labeled with the term “culture” or “cultured” in their product names or standards of identity (e.g., “cell culture[d]”), would labeling differentiation be necessary to distinguish these products from other types of foods where the term “culture” or “cultured” is used (such as “cultured celery powder”)?**

At this point in the development of the cultivated food industry, it would be premature to impose any singular descriptive term on meat or poultry products comprised of or containing cultured animal cells,

¹³ *Id.* at 651.

¹⁴ A 2020 Gallup poll found that about a quarter of American adults had cut back on meat consumption over the previous 12 months, and that a third of American adults ate meat “occasionally,” “rarely,” or “never.” Of those surveyed who said that they were eating “less,” “rarely,” or “never,” three of their top four reasons for their reduced meat intake were food safety, the environment, or animal welfare. All three of those concerns are relevant to a potential choice to consume cultivated meat. Justin McCarthy and Scott DeKoster, *Nearly One in Four in U.S. Have Cut Back on Eating Meat*, Gallup (January 2020), Exhibit E.

as doing so could restrict the industry’s ability to respond to consumer preferences and opinions that may evolve once the products are in the marketplace.

Currently, industry practices and consumer studies show a growing consensus around the use of “cultivated” as the preferred terminology for meat or poultry products comprised of or containing cultured animal cells. One recent Good Food Institute study found that 75% of surveyed companies developing such products preferred the term “cultivated” to identify and market those products to consumers.¹⁵ For the consumer, “cultivated” evokes an accurate picture of the process used to produce and grow these meat and poultry products, while maintaining tonal neutrality when compared to conventionally slaughtered meat.¹⁶ Early consumer studies also have indicated that consumers prefer the term “cultivated.”¹⁷ “Cultivated” draws a comprehensible and biologically accurate analogy to plant cultivation—just as plants are “cultivated” by nurturing a seed or cutting in a nutrient-rich environment, so too is cultivated meat grown by nurturing animal cells in a nutrient-rich environment.

Using the descriptor “cultivated” rather than “cultured” also would avoid any consumer confusion with existing cultured food products (such as food created using fermentation and bacterial cultures like pickles, yogurt, kombucha, etc.). Although “cultured” is scientifically accurate, “cultivated” is equally accurate and avoids confusing associations with these other types of cultured foods. USDA-FSIS should not go so far as to prohibit a cultivated meat company from using “cultured” on its packaging, but we expect that industry consensus will continue to evolve around the preferred nomenclature for meat or poultry products comprised of or containing cultured animal cells.

Alternatively, if USDA-FSIS does mandate certain descriptive nomenclature for such labels, the agency should concurrently require labeling of slaughter-based meat and poultry products as such. If USDA-FSIS determines that the process by which a meat or poultry product is produced is relevant enough to require labeling, this should be equally relevant to delineate whether the meat or poultry product came from the cell cultivation process or a slaughtered animal. Among other reasons, this will enable consumers to make informed choices regarding the degree of harm to animals required to produce such products and the food safety risks associated with conventionally slaughtered meat and poultry products.

If the terms “cultivated” and “slaughtered” meat are used to differentiate types of meat and poultry products, both cultivated and slaughtered meat producers will benefit from a clear distinction between the two types of products. Indeed, the conventional meat industry has long sought points of differentiation between slaughtered meat and plant-based meat, and even successfully lobbied for state legislation to restrict the use of terms like “burger” in plant-based meat alternatives.¹⁸ In deference to this concern, some

¹⁵ Good Food Institute, *Cultivated Meat: A Growing Nomenclature Consensus*, <https://gfi.org/blog/cultivated-meat-a-growing-nomenclature-consensus/>.

¹⁶ Good Food Institute, *Meat Cultivation Narrative*, https://gfi.org/wp-content/uploads/2021/02/Cultivated-Meat-Narrative_11_2019.pdf.

¹⁷ Szejda, K.; Bryant, C.J.; Urbanovich, T., *US and UK Consumer Adoption of Cultivated Meat: A Segmentation Study*, 10, 1050 Foods 1-23, 14 (2021), Exhibit F.

¹⁸ See, e.g., Mo.Rev.Stat. § 265.494(7) (Identifying “Misrepresenting the cut, grade, brand or trade name, or weight or measure of any product, or misrepresenting a product as meat that is not derived from harvested production livestock or poultry” as a “misleading or deceptive practice” subject to criminal and civil penalties).

states have gone so far as to ban the sale of cell-cultured meat and poultry products labeled as “meat.”¹⁹ Therefore, cultivated meat and poultry producers would benefit from federal labeling guidelines that allowed for clear, accurate, and effective consumer-facing communications, as well as from the imprimatur of USDA-FSIS approval of their product.

As cultivated meat and poultry products enter the marketplace, they initially are expected to carry a higher cost than their slaughter-based analogues.²⁰ Companies bringing these products to market may seek to use labeling claims to help explain the higher cost to consumers and inform them of various benefits associated with cultivated meat and poultry products (e.g., slaughter-free, etc.). Indeed, there are preliminary indications that U.S. consumers will be willing to pay more for cultivated meat.²¹ Accordingly, USDA-FSIS should allow these types of *voluntary* labeling claims, so long as they are provable and supported by relevant evidence. USDA-FSIS should be able to evaluate such claims easily on a case-by-case basis as labels for such products are submitted to USDA-FSIS for approval.

More broadly, overly restrictive labeling requirements for cultivated meat products will impede fair competition in the marketplace and could provide an unnecessary and inappropriate disincentive to investors in this burgeoning domestic food industry. Those consequences likely would drive production abroad and put the U.S. at risk of losing its leadership status in the cellular agriculture field. To preserve America’s leadership in this promising field and its advantageous position for future global export,²² USDA-FSIS should carefully weigh the benefits of any labeling approach against the potential for stifling innovation.

3. If a meat or poultry product were comprised of both slaughtered meat or poultry and cultured animal cells, what unique labeling requirements, if any, should be required for such products?

If a meat or poultry product is voluntarily labeled as being comprised of cultured animal cells, such as employing the term “cultivated,” then that product should only contain cultivated meat or poultry as substantiated by evidence verified by USDA-FSIS. If a product like ground beef or a processed chicken nugget is an indistinguishable intermixture (i.e., 60% cultivated chicken, 40% slaughtered chicken), and the producer wishes to make a claim on the label that the product contains cultivated meat or poultry products, then the label should disclose that the product is a blend, and delineate the percentages of cultivated and slaughtered meat or poultry products, again as substantiated by evidence verified by USDA-FSIS. These components would not necessarily need to be listed separately on an ingredients list, but any claim that a product consists of or contains cultivated meat should be accurate and verifiable. Disclosing the proportion of both cultivated and slaughtered meat or poultry in products employing cultivated labeling

¹⁹ See, e.g., Miss. Code Ann. §75-35-15(4) (“A food product that contains cultured animal tissue produced from animal cell cultures outside of the organism from which it is derived shall not be labeled as meat or a meat food product.”).

²⁰ See generally Open Philanthropy, *Animal Product Alternatives* (December 2015), Exhibit G.

²¹ Szejda, K.; Bryant, C.J.; Urbanovich, T., *supra* note 17.

²² 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 labeling approach for meat or poultry products comprised of or containing cultured animal cells should be science-based, and restrictive labeling requirements on cultivated meat and poultry products could negatively impact trade.

claims would ensure that consumers are aware of the relative composition of such products and are not misled or deceived into purchasing food items claiming to be comprised of ingredients they contain only in small amounts.

4. What term(s), if used in the product name of a food comprised of or containing cultured animal cells, would be potentially false or misleading to consumers? For each term, please provide your reasoning.

Terms such as “imitation,” “fake,” “lab grown,” and “in vitro” should not be used in product names of foods comprised of or containing cultured animal cells, as they are inaccurate descriptors for such products and therefore could be potentially false or misleading to consumers.

Using “imitation” and “fake” in the product names of food comprised of or containing cultured animal cells would be potentially false and misleading to consumers because most, if not all, cultivated meat and poultry products will be cellularly indistinguishable from slaughtered meat and poultry products. Additionally, “imitation” has an existing regulatory definition when applied to food: “A food shall be deemed to be an imitation...if it is a substitute for and resembles another food but is *nutritionally inferior* to that food.”²³ Because cultivated meat and poultry products are expected to be molecularly identical and nutritionally equivalent to their slaughtered analogues, falsely naming them as “imitation” would mislead consumers into thinking that such products are nutritionally inferior.

Using “imitation” or “fake” in the product names of food comprised of or containing cultured animal cells also would cause the cultivated meat or poultry product to be misbranded. This is vitally important as some consumers may have allergies to certain meat or poultry products and thus will need to know that a cultivated product is genetically the same as its slaughtered counterpart, rather than an imitation that has different ingredients or qualities.

Similarly, slaughtered meat should not have exclusive license to the labeling or marketing claim of “real” meat. Because both products are expected to be identical in composition, cultivated meat and poultry products will be just as “real” as their slaughtered analogues, in the same way that they are not “imitations.”

Using the term “lab-grown” in the product names of food comprised of or containing cultured animal cells would be false and misleading to consumers because cultivated meat and poultry products are expected to be cultivated in production facilities, not laboratories, similar to the way beer is brewed, or bread is baked, at both large and smaller scale.²⁴ While cultivated meat and poultry products may be developed and tested in laboratory settings, this element of their provenance is indistinguishable from the majority of other products in the United States’ industrial-scale food supply—from ice cream²⁵ to potato

²³ 21 CFR 101.3(e)(1) (emphasis added).

²⁴ See Adele Peters, *Take a look inside this shiny, industrial ‘cultivated meat’ factory of the future*, Fast Company (November 4, 2021), <https://www.fastcompany.com/90692577/take-a-look-inside-this-shiny-industrial-cultivated-meat-factory-of-the-future>.

²⁵ Allen Gannett, *How Ben & Jerry’s knows what ice cream you’ll crave in two years*, Fast Company (June 2018), <https://www.fastcompany.com/40581334/how-ben-jerrys-knows-what-ice-cream-youll-crave-in-two-years>.

chips²⁶ to (slaughtered) beef jerky²⁷ and pork bellies.²⁸ Just as none of these food items developed in laboratories are misleadingly required to be designated as “lab-grown,” neither should cultivated meat or poultry products.

The term “in vitro” is Latin for “in glass,” and commonly is used to refer to processes that occur in a test tube or petri dish.²⁹ Such laboratory tools indeed may be used in the initial development of cultivated meat and poultry products, just as they are with many conventional U.S. food products. But using “in vitro” in the product names of food comprised of or containing cultured animal cells would be false or misleading to consumers because test tubes and petri dishes are unlikely to be used to produce finished cultivated meat and poultry products at scale for the consumer market. Furthermore, Americans are likely to associate “in vitro” with the “in vitro fertilization” process used as a reproductive fertility treatment for humans, and thereby draw an inaccurate association with embryonic development. That association is likely to mislead and confuse consumers about the origins and process of making these food items, because the production of cultivated meat and poultry products does not involve the creation of fertilized animal embryos.

5. What term(s), if used in the product name of a food comprised of or containing cultured animal cells, would potentially have a negative impact on industry or consumers? For each term, please provide your reasoning.

Terms such as “imitation,” “fake,” “lab grown,” and “in vitro” should not be used in product names of foods comprised of or containing cultured animal cells, as they are inaccurate descriptors for such products and therefore could potentially have a negative impact on industry or consumers.

Using “imitation” and “fake” in the product names of food comprised of or containing cultured animal cells potentially would have a negative impact on industry and consumers because most, if not all, cultivated meat and poultry products will be cellularly indistinguishable from slaughtered meat and poultry products. As a result, using “imitation” and “fake” would be inaccurate and prejudicial, potentially causing some consumers to avoid such products, or encouraging other consumers to purchase them mistakenly believing they are physically different in composition from their slaughtered counterparts.

Additionally, “imitation” has an existing regulatory definition when applied to food: “A food shall be deemed to be an imitation...if it is a substitute for and resembles another food but is *nutritionally inferior* to that food.”³⁰ Because cultivated meat and poultry products are expected to be molecularly identical and nutritionally equivalent to their slaughtered analogues, falsely naming them as “imitation” would give consumers the negative impression that such products are nutritionally inferior and negatively impact producers by potentially reducing sales based on inaccurate descriptions.

²⁶ Alex Beggs, *There’s an Entire Industry Dedicated to Making Foods Crispy, and It Is WILD*, Bon Appetit (February 2020), <https://www.bonappetit.com/story/crispy>.

²⁷ See, e.g., Texas A & M University, *Texas Aggie Brand Beef Jerky: History*, <https://beefjerky.tamu.edu/history/>.

²⁸ Amanda Little, *Tyson Isn’t Chicken*, Bloomberg (Aug. 15, 2018) (examining a pork belly at the “Discovery Center, a laboratory for product innovation at Tyson Foods Inc. in Springdale, Ark.”), <https://www.bloomberg.com/news/features/2018-08-15/tyson-s-quest-to-be-your-one-stop-protein-shop>.

²⁹ *in vitro*, Online Etymology Dictionary (“1892, scientific Latin; “in a test tube, culture dish, etc.,” literally “in glass,” from Latin vitrum “glass”).

³⁰ 21 CFR 101.3(e)(1) (emphasis added).

Using “imitation” or “fake” in the product names of food comprised of or containing cultured animal cells also would cause the cultivated meat or poultry product to be misbranded with potentially life-threatening negative consequences for consumers. This is vitally important as some consumers may have allergies to certain meat or poultry products and thus will need to know that a cultivated product is genetically the same as its slaughtered counterpart, rather than an imitation that has different ingredients or qualities.

Using the term “lab-grown” in the product names of food comprised of or containing cultured animal cells would be inaccurate and prejudicial with potentially negative impacts on consumption because cultivated meat and poultry products are expected to be cultivated in production facilities, not laboratories, similar to the way beer is brewed, or bread is baked, at both large and smaller scale.³¹ While cultivated meat and poultry products may be developed and tested in laboratory settings, this element of their provenance is indistinguishable from the majority of other products in the United States’ industrial-scale food supply—from ice cream³² to potato chips³³ to (slaughtered) beef jerky³⁴ and pork bellies.³⁵ Just as none of these food items developed in laboratories are required to be negatively designated as “lab-grown,” neither should cultivated meat or poultry products.

The term “in vitro” is Latin for “in glass” and commonly is used to refer to processes that occur in a test tube or petri dish.³⁶ Such laboratory tools indeed may be used in the initial development of cultivated meat and poultry products, just as they are with many conventional U.S. food products. But using “in vitro” in the product names of food comprised of or containing cultured animal cells would be inaccurate and prejudicial to consumers because test tubes and petri dishes are unlikely to be used to produce finished cultivated meat and poultry products at scale for the consumer market. Furthermore, Americans are likely to negatively associate “in vitro” with the “in vitro fertilization” process used as a reproductive fertility treatment for humans, and thereby draw an inaccurate association with embryonic development. Using “in vitro” in the product names of food comprised of or containing cultured animal cells thus would have a negative impact on consumption due to the inaccurate association with human fertility treatments—and would be especially misleading to consumers given that the production of cultivated meat and poultry products does not involve the creation of fertilized animal embryos.

6. Should names for slaughtered meat and poultry products established by common usage (e.g., Pork Loin), statute, or regulation be included in the names or standards of identity of such products derived from cultured animal cells?

- a. If so, is additional qualifying language necessary? What qualifying terms or phrases would be appropriate?**
- b. Do these names, with or without qualifying language, clearly distinguish foods comprised of or containing cultured animal cells from slaughtered products?**

³¹ See Peters, *supra* note 24.

³² Gannett, *supra* note 25.

³³ Beggs, *supra* note 26.

³⁴ See, e.g., Texas A & M University, *supra* note 27.

³⁵ Little, *supra* note 28.

³⁶ Online Etymology Dictionary, *supra* note 29.

Existing terms for meat and poultry products established by common usage, statute, or regulation should be permitted to be used in the names of analogous products derived from cultured animal cells. This is the most accurate nomenclature approach because cultivated meat and poultry products will be substantially the same and have comparable characteristics as their counterpart slaughtered meat and poultry products. Allowing such commonly understood product names would enable consumers to know more precisely what type of product they are purchasing or consuming, reducing potential consumer confusion. However, as detailed further in our response to Question 8 below, USDA-FSIS does not need to establish new standards of identity for food products derived from cultured animal cells.

USDA-FSIS also should allow the use of common or usual meat and poultry terms in product names specified in standards of identity on cultivated meat and poultry product labels because preventing such use is likely to be unconstitutional. Further, any nomenclature or labeling restrictions USDA-FSIS requires 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.³⁷ A nomenclature scheme that allows for the use of common or usual meat and poultry terms is consistent with longstanding USDA policy that balances consumer safety with consumer choice and leaves space for fair competition. 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 meat and poultry terms.³⁸ For example, such labeling differentiation or disclosure is not required on meat from cloned animals and their progeny.³⁹

Conversely, a labeling scheme that *bans* the use of common meat and poultry terms in the names of cultivated meat and poultry products, or an approach that requires unnecessary *disclosures*, likely will violate the First Amendment, and may be deemed arbitrary and capricious under the Administrative Procedure Act. Because there will be no difference in the safety and composition of finished cultivated meat and poultry products and their slaughtered counterparts, USDA-FSIS would lack sufficient justification to prohibit the use of common or usual meat and poultry terms in the names of analogous products derived from cultured animal cells—as doing so would be more restrictive than necessary to advance the agency's asserted interests.

As outlined in our responses to Questions 1 and 2 above, no additional qualifying language is necessary to distinguish foods comprised of or containing cultured animal cells from slaughtered products, because the consumer products will be physically and functionally comparable to each other. At this point in the development of the cultivated food industry, it also would be premature to impose any singular descriptive term on cultivated meat and poultry products, as doing so could restrict the industry's ability to respond to consumer preferences and opinions that may evolve once the products are in the marketplace.

³⁷ *Zauderer v. Off. of Disc. Counsel of S. Ct. of Ohio*, 471 U.S. 626, 651 (1985).

³⁸ *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); Fassler, *supra* note 2, (“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”).

³⁹ *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.”).

7. Should terms that specify the form of meat or poultry products (such as “fillet”, “patty”, or “steak”) be allowed to be included in or to accompany the name or standard of identity of foods comprised of or containing cultured animal cells?

a. Under what circumstances should these terms be used?

b. What information would these terms convey to consumers?

Yes. Allowing names that accurately identify the *form* of foods comprised of or containing cultured animal cells will allow consumers to make specific purchasing decisions about which products best suit their intended use (i.e., stew beef vs. burger). USDA-FSIS should allow these terms to be used wherever they are useful and/or mandated by the current USDA standards of identity for meat and poultry products. As mentioned in our response to Question 6 above, because most, if not all, cultivated meat and poultry products will be substantially the same and have comparable characteristics as their counterpart slaughtered meat and poultry products, allowing terms that specify the form of cultivated meat and poultry products will better enable consumers to know more precisely what type and style of product they are purchasing or consuming. Again, as detailed further in our response to Question 8 below, USDA-FSIS does not need to establish new standards of identity for food products derived from cultured animal cells.

8. Should FSIS establish a regulatory standard of identity under its authorities in the FMIA and the PPIA (21 U.S.C. 607(c) and 457(b)) for foods comprised of or containing cultured animal cells?

a. If so, what would be the standard and how might compliance with the standard be verified?

b. If so, what would be the labeling terminology for products that do and do not meet a formal standard of identity? What would be the anticipated categories of use? For example, mechanically separated poultry that does not meet the standards of identity outlined in 9 CFR 381.173 may be diverted for production in broths and bases, as well as reaction flavors, i.e., flavors produced by the heating of the protein source in the presence of a reducing sugar.

c. If so, what are the benefits and costs to industry if the standard of identity is established? Please provide quantitative and qualitative feedback in your response and explain the basis of any quantitative estimates.

d. If so, what are the consumer benefits and costs to the standard of identity recommended?

No. To promote this Administration’s goals of maximizing food technology flexibility, preventing significant and unnecessary delays, and facilitating innovation, USDA-FSIS should not establish new standards of identity for foods comprised of or containing cultured animal cells. Standards of identity specify recipes or compositional parameters that products must meet in order to use standardized terms in the labeling of such products.⁴⁰ Because most, if not all, cultivated meat and poultry products will be identical in physical composition and function to their slaughter-based counterparts, and likely carry less

⁴⁰ 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>.

risk due to the lack of potential fecal contamination and other slaughter-associated hazards, these products can conform with the material aspects of existing standards of identity without increasing any risk to the consumer. Thus, foods comprised of or containing cultured animal cells can be labeled with the respective standardized terms without being “misbranded.”⁴¹

In 2019, HHS-FDA, which shares jurisdiction over establishing meat and poultry product standards of identity,⁴² solicited public input on ways to systematically modernize standards of identity to “promote industry innovation and provide flexibility to encourage manufacturers to produce healthier foods,”⁴³ implicitly recognizing the rigidity of the current standards of identity structure. The standards of identity modernization process began in 1995 when the USDA-FSIS and HHS-FDA began considering how to update their standards of identity “to grant the flexibility necessary for timely development and marketing of products that meet consumer needs, while at the same time providing consumer protection.”⁴⁴ As USDA-FSIS recognized at 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.”⁴⁵ Furthermore, in 2005, USDA-FSIS and HHS-FDA jointly issued a proposal acknowledging that regulations should not limit technology, which the agencies expected to lead to better quality and less expensive products for consumers.⁴⁶ Thus, 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.⁴⁷

In the case of foods comprised of or containing cultured animal cells created using a “suitable alternative manufacturing process,”⁴⁸ the “food technology used to prepare the standardized food...does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality, or safety of the food.”⁴⁹ Thus, cultivated meat and poultry products already should be considered to conform with the material aspects of existing standards of identity and regulatory definitions for meat and poultry products—eliminating the need to establish new standards of identity for foods comprised of or containing cultured animal cells.

⁴¹ See 21 U.S.C. § 601(n)(7). 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.” *Id.*

⁴² 21 U.S.C. § 607(c) (meat); 21 U.S.C. § 457(b) (poultry).

⁴³ *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>.

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

⁴⁵ *Id.* (citing 61 Fed. Reg. 47453 (Sept. 9, 1996)).

⁴⁶ *Id.* at 29222.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

Moreover, establishing new standards of identity for foods comprised of or containing cultured animal cells under the existing framework will create unnecessary delays and result in rigid requirements that likely will impair future innovation. These consequences have the potential to reduce the ability of U.S. producers to create healthier, more sustainable, and more humane products. The technology and science of cultivated meat and poultry products is developing rapidly and will continue to evolve. Not only would establishment of new standards of identity be time-consuming and resource-intensive, but standards of identity for cultivated meat and poultry products likely would not be flexible enough to accommodate future technological advances or as-yet-unforeseeable products.

There is no need to establish new regulatory standards of identity for foods comprised of or containing cultured animal cells, as cultivated meat products already comply with the statutory definition of “meat food products” in the Meat Products Inspection Act (MPIA).⁵⁰ However, USDA-FSIS should issue a Directive clarifying that because these products are materially indistinguishable from slaughtered meat products, they will not be considered “misbranded” under the MPIA.

An interpretive problem potentially arises under the Poultry Products Inspection Act (PPIA),⁵¹ which defines “poultry product” as “any poultry *carcass*, or part thereof; or any product which is made wholly or in part from any poultry *carcass* or part thereof...”⁵² Cultivated poultry cannot be said to be derived from a poultry “carcass” under the plain meaning of that term. Therefore USDA-FSIS should issue a Directive clarifying that because such products are expected to be materially indistinguishable from slaughtered poultry and poultry products, they will not be considered “misbranded” under the PPIA.

Issuing such Directives would prevent unnecessary administrative delays, while promulgating clear guidelines for both industry and USDA-FSIS inspectors to follow as this evolving cultivated meat and poultry industry continues to develop.

9. What nutritional, organoleptic (e.g., appearance, odor, taste), biological, chemical, or other characteristics, material to consumers’ purchasing and consumption decisions, vary between slaughtered meat or poultry products and those comprised of or containing cultured animal cells?

The nutritional and organoleptic characteristics of meat and poultry products comprised of or containing cultured animal cells are unlikely to differ significantly from their slaughtered counterparts. However, cultivated meat and poultry products may have the potential to improve upon the nutritional profile of slaughtered meat and poultry products, given that the cultivation process will enable producers to control the proportions of intramuscular fat, levels of vitamin D, and other nutritional elements of cultivated meat and poultry products.

Additionally, because cultivated meat and poultry products will be produced in facilities that are not exposed to fecal matter and other contaminants present in conventional abattoirs and processing plants, the risk of contamination by most foodborne illnesses should be reduced substantially for cultivated meat and poultry products.⁵³

⁵⁰ 21 U.S.C.A. § 601 (j).

⁵¹ 21 U.S.C.A. § 451 – 472.

⁵² 21 U.S.C.A. § 453 (f).

⁵³ Cookson Beecher, *Clean, safe, humane – producers say lab meat is a triple win*, Food Safety News (Jan. 18, 2017), <https://www.foodsafetynews.com/2017/01/clean-safe-humane-producers-say-lab-meat-is-a-triple-win/>.

The production process for cultivated meat and poultry products also eliminates the need for antibiotic use during cultivation.⁵⁴ According to the World Health Organization, in some countries “approximately 80% of total consumption of medically important antibiotics is in the animal sector, largely for growth promotion in healthy animals.”⁵⁵ Domestically, it is estimated that “65% of medically important antibiotics sold in the United States are being used in food-producing species, compared with 35% in humans.”⁵⁶ These vast amounts of antibiotics fed to animals to produce slaughtered meat and poultry products pose a serious risk to human health by “reducing the effectiveness of antimicrobial drugs for treating human disease.”⁵⁷

Cultivated meat and poultry products additionally are expected to have a reduced environmental impact as compared to slaughtered meat and poultry products. Although precise calculations are currently unavailable, many experts predict that cultivated meat and poultry will require less energy, less water, and less land to produce (addressing concerns of deforestation to grow animal feed).⁵⁸ Cultivated meat and poultry products also are predicted to produce fewer greenhouse gas emissions than slaughtered meat and poultry products, and therefore could help reduce adverse impacts from climate change.⁵⁹

Cultivated meat and poultry products also have the potential to address global food insecurity—as production can occur almost anywhere in the world, rather than only in regions that have suitable geography and climate conditions to both grow feed crops and raise live animals on a large scale. The potential for cultivated meat and poultry products to be produced more quickly than slaughtered products also may allow for faster and more efficient supply chain distribution to feed the demands of a growing global population.⁶⁰ As the cultivated meat and poultry sector scales, production costs undoubtedly will decrease, making these products more accessible to a broad range of consumers. Additionally, cultivated meat and poultry products can help alleviate meat shortages that result from animal contamination and disease, such as the 2014–15

⁵⁴ Post, *supra* note 6.

⁵⁵ Christian Lindmeier, *Stop using antibiotics in healthy animals to prevent the spread of antibiotic resistance*, World Health Organization (Nov. 17, 2017), Exhibit H.

⁵⁶ Chris Dall, *FDA reports another rise in antibiotic sales for livestock*, Center for Infectious Disease Research and Policy (Dec. 16, 2020), Exhibit I.

⁵⁷ *Antimicrobial Resistance*, U.S. Food & Drug Administration (“Antimicrobial use in animals can contribute to the emergence of antimicrobial resistance in bacteria that may be transferred to humans, thereby reducing the effectiveness of antimicrobial drugs for treating human disease.”), <https://www.fda.gov/animal-veterinary/safety-health/antimicrobial-resistance>.

⁵⁸ Kate Whitling, *How soon will we be eating lab-grown meat?*, World Economic Forum (Oct. 16, 2020), <https://www.weforum.org/agenda/2020/10/will-we-eat-lab-grown-meat-world-food-day/>; Raychel E. Santo et al., *Considering Plant-Based Meat Substitutes and Cell-Based Meats: A Public Health and Food Systems Perspective*, *Frontiers in Sustainable Food Systems* (Aug. 31, 2020), Exhibit J.

⁵⁹ See, e.g., Hanna L. Tuomisto & M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, 45 ENVTL. SCI. & TECH. 6117 (2011), Exhibit K; Zhi-chang Sun, Qun-li Yu & Lin Han, *The Environmental Prospects of Cultured Meat in China*, 14 J. INTEGRATIVE AGRIC. 234 (2015), Exhibit L; 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), Exhibit M.

⁶⁰ The Borgen Project, *Can Lab-Grown Meat Fight Poverty?* (February 2021), <https://borgenproject.org/lab-grown-meat/>.

avian flu outbreak that resulted in the death or culling of more than 50 million chickens and turkeys in this country.⁶¹

Cultivated meat and poultry products also have the potential to allow consumers to make purchasing choices that reduce their own impact on animal welfare or cruelty, while still consuming food items that have comparable characteristics and are substantially the same as existing slaughtered products already familiar to them. Therefore, for consumers who value animal welfare, as studies show 61% of consumers do,⁶² cultivated meat and poultry products present an attractive, ethical option. By their very nature, cultivated meat and poultry products have the potential to drastically reduce the need to breed, raise, and slaughter the billions of animals consumed each year in the United States alone,⁶³ significantly reducing animal suffering.⁶⁴

10. Should any of the definitions for “meat”, “meat byproduct”, or “meat food product” found in 9 CFR 301.2 be amended to specifically include or exclude foods comprised of or containing cultured animal cells?

The definitions of “meat,” “meat byproduct,” and “meat food product” should not be amended to specifically include or exclude foods comprised of or containing cultured animal cells because cultivated meat products already comply with those regulatory definitions.⁶⁵

However, contemplating the development of animal food derived from cultivated meat and poultry products, USDA-FSIS and FDA should re-consider the regulatory definition of “animal food,” currently defined in 9 CFR 301.2 as “[a]ny article intended for use as food for dogs, cats, or other animals derived wholly, or in part, from the carcass or parts or products of the carcass of any livestock...”⁶⁶ By 2025, the global market for pet food made from cultivated meat and poultry products is expected to reach \$206.6 million.⁶⁷ Only four nations currently consume more meat than is eaten by American pets each year, and dogs and cats are estimated to account for up to 30 percent of the environmental impact of U.S. meat

⁶¹ Sean Ramos, Matthew MacLachlan, and Alex Melton, USDA-ERS, *Impacts of the 2014-2015 Highly Pathogenic Avian Influenza Outbreak on the U.S. Poultry Sector* (December 2017), <https://www.ers.usda.gov/webdocs/outlooks/86282/ldpm-282-02.pdf?v=539>.

⁶² Gallup, *Nutrition and Food* (2019), Exhibit N. (Indicating that 61% of consumers are likely to choose a product identified as “Certified humane, cage free or dolphin safe” over a competing product with no such label either always [13%], often [22%] or sometimes [26%]).

⁶³ See, e.g., David Julian McClements, *FUTURE FOODS: HOW MODERN SCIENCE IS TRANSFORMING THE WAY WE EAT* 337 (2019) (“[T]he fact that [cultivated] 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, *supra* note 59; Z.F. Bhat & Hina Bhat, *Animal-Free Meat Biofabrication*, 6 AM. J. FOOD TECH. 441, 453 (2011), Exhibit O (“[A cultivated meat] system reduces animal use in the meat production system...”).

⁶⁴ Cultivated meat and poultry production 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, *supra* note 59 (“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), Exhibit P.

⁶⁵ 9 CFR 301.2.

⁶⁶ *Id.*

⁶⁷ Lara Bandoim, *Cultured Meat Companies Want To Transform The Pet Food Industry*, *Forbes* (May 2021), <https://www.forbes.com/sites/lanabandoim/2021/05/24/cultured-meat-companies-want-to-transform-the-pet-food-industry/?sh=7df010a07422>.

consumption.⁶⁸ USDA-FSIS should issue a Directive clarifying that animal food derived from cultivated meat products will not be considered “misbranded” under 9 CFR 301.2. Such guidance would bring certainty and uniformity to the developing cultivated meat and poultry derived pet food industry and encourage further innovation by domestic producers.

11. Should any of the definitions for “poultry product” or “poultry food product” found in 9 CFR 381.1 be amended to specifically include or exclude foods comprised of or containing cultured animal cells?

No. As discussed above in response to Question 8, because the regulatory definitions for “poultry product” and “poultry food product” found in 9 CFR 381.1 derive from the statutory definitions that include the term “carcass,” USDA-FSIS instead should issue a Directive clarifying that cultivated poultry and poultry products will not be considered “misbranded” under the PPIA.

USDA-FSIS and FDA also should re-consider the analogous regulatory definition of “animal food,” defined in 9 CFR 381.1 as “any poultry carcass or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof...”⁶⁹ By 2025, the global market for pet food made from cultivated meat and poultry products is expected to reach \$206.6 million.⁷⁰ Only four nations currently consume more meat than is eaten by American pets each year, and dogs and cats are estimated to account for up to 30 percent of the environmental impact of U.S. meat consumption.⁷¹ USDA-FSIS should issue a Directive clarifying that animal food derived from cultivated poultry products will not be considered “misbranded” under 9 CFR 381.1. Such guidance similarly would bring certainty and uniformity to the developing cultivated meat and poultry-derived pet food industry and encourage further innovation by domestic producers.

12. Should FSIS-regulated broths, bases, and reaction flavors produced from cultured animal cells be required to declare the source material in the product name, ingredient sub-listing, or elsewhere on the label?

No. FSIS-regulated broths, bases, and reaction flavors produced from cultured animal cells should not be required to declare the source material in the product name, ingredient sub-listing, or elsewhere on the label, unless the label or name of such products makes *claims* about being produced from cultured animal cells. If such claims are made on the labels or names of such products, then USDA-FSIS should require those claims to be substantiated by evidence that the products in question do indeed originate from cultured animal cells rather than slaughtered meat or poultry products. If the broths, bases, and reaction flavors are produced from a *blend* of cultured animal cells and slaughtered meat or poultry products, and the producer wishes to make a claim on the label that the product contains cultivated meat or poultry products, then the label should disclose that the product is a blend and delineate the percentages of cultivated and slaughtered meat or poultry products, again as substantiated by evidence verified by USDA-FSIS.

⁶⁸ Danny Funt, *Pets can help fight climate change with an insect-based diet. Owners just need to come around to the idea*, Washington Post (Sept. 21, 2021), <https://www.washingtonpost.com/climate-solutions/2021/09/21/pet-food-sustainable-bugs-insects/>.

⁶⁹ 9 CFR 381.1.

⁷⁰ Bandoim, *supra* note 67.

⁷¹ Funt, *supra* note 68.

13. Should the presence of cultured animal cells in further processed products regulated by FSIS, such as a lasagna made with cell cultured beef cells as an ingredient, be qualified on the product label? If so, how should this be qualified?

No. The presence of cultured animal cells in further processed products regulated by FSIS, such as a lasagna made with cell cultured beef cells as an ingredient, should not be qualified on the product label unless the labels of such products make claims about being produced from cultured animal cells. If such claims are made on the labels of such products, then USDA-FSIS should require those claims to be substantiated by evidence that the products in question do indeed originate from cultured animal cells rather than slaughtered meat or poultry products. If the further processed products regulated by FSIS are produced from a *blend* of cultured animal cells and slaughtered meat or poultry products, and the producer wishes to make a claim on the label that the product contains cultivated meat or poultry products, then the label should disclose that the product is a blend and delineate the percentages of cultivated and slaughtered meat or poultry products, again as substantiated by evidence verified by USDA-FSIS.

14. What label claims are likely to appear on FSIS-regulated products comprised of or containing cultured animal cells? Should FSIS develop new regulations or guidance on such claims to ensure they are neither false nor misleading?

Cultivated meat producers should be permitted to make claims such as “slaughter-free” and “nitrate-free” and other credence claims so long as they can sufficiently substantiate those claims. Language 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—as long as the speech is not inherently false, deceptive, misleading, or promoting illegal activity.⁷² At this time, it is not necessary to develop novel regulation in this area, as existing consumer protection law already contemplates the types of false and misleading claims that may give rise to grievances with respect to cultivated meat and poultry products. We expect that the cultivated meat and poultry industry will make claims about the wholesomeness of their products, as well as accurate claims about the reduced risk of fecal-based foodborne pathogens, environmental impact, and the humaneness of the cultivated meat production process relative to conventional slaughtered meat—all of which can be verified objectively and addressed by such existing consumer protection measures.

Courts have upheld regulations permitting absence claims such as “nitrate-free” on package labels, even where they might create competitive pressure on other producers.⁷³ In evaluating such absence claims, courts do not consider potential competitive harm.⁷⁴ Documentation requirements should be consistent with current USDA-FSIS policy for applicable or similar claims, such as “negative claims.”⁷⁵ Consumers seek

⁷² *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 564.

⁷³ *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”).

⁷⁴ *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.”)).

⁷⁵ *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->

out new products for many reasons, including to avoid allergens or other unhealthful substances that currently may be found in slaughter-based animal products. Such consumers should be able to identify products that meet their personal preferences. Permitting companies to make credence claims, so long as they can substantiate them on cultivated meat and poultry product labels, will materially improve transparency and consumer choice regarding the purchase of meat and poultry products in the marketplace.

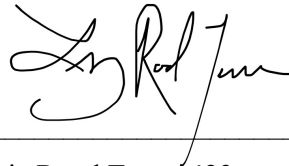
Conclusion

The Harvard Law School Animal Law & Policy Clinic and Food Law and Policy Clinic thank USDA-FSIS for considering these comments. As outlined above, ALPC and FLPC recommend that USDA-FSIS adopt a labeling approach for meat or poultry products comprised of or containing cultured animal cells that does not overly restrict speech, respects the First Amendment, and fosters consumer choice and technological innovation. For all the foregoing reasons, USDA-FSIS should not issue labeling requirements for cultivated meat and poultry products, should not create new standards of identity for such products, and should not prohibit the use of common or usual meat and poultry terms or product names specified in existing standards of identity. If the agency nevertheless decides to take such action, it should adhere to the constitutional, consumer, and competitive concerns expressed herein.

Respectfully Submitted,



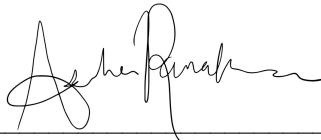
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d066ac12651b/labeling-guideline-bioengineered.pdf?MOD=AJPERES; USDA, NEGATIVE INGREDIENT LABELING, POLICY MEMORANDUM 019B (Aug. 18, 1994), https://www.fsis.usda.gov/wps/wcm/connect/92485d36-be7f-451b-9153-7a921b13dc72/Policy_Memos_101818.pdf?MOD=AJPERES.