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Administrator Paul Kiecker
United States Department of Agriculture
Food Safety and Inspection Service
Room 2534 South Building
1400 Independence Avenue SW
Washington, DC 20250-3700

By email to fsispetitions@usda.gov

RE: FSIS Petition No. 20-03
Submitted by Harvard Law School Animal Law & Policy Clinic

Dear Administrator Kiecker:

Thank you for the opportunity to comment on the letter to the U.S. Department of Agriculture Food Safety & Inspection Service (FSIS) from the Harvard Law School Animal Law & Policy Clinic, which FSIS has designated as Citizen Petition No. 20-03 (the "Petition"). As explained fully below, the Good Food Institute (GFI) writes in broad support of the regulatory framework described in that Petition.

GFI is an international 501(c)(3) nonprofit organization dedicated to harnessing innovation to create a healthy, sustainable, and just global food supply. Our team of scientists, entrepreneurs, and policy experts focus on using markets and technological innovation to transform our food supply. We believe that cultivated meat (also called "cell-based meat" or "cultured meat") will play an important role in building the food supply of the future, and we applaud Secretary Perdue for prioritizing United States leadership in the research, development, and production of cultivated meat.[1]

As Secretary Perdue has noted, American global leadership in cultivated meat innovation also calls for American regulatory leadership and regulatory clarity. An unnecessarily restrictive regulatory regime is inimical to the innovation and growth necessary for the United States to lead the world in alternative proteins like cultivated

[1] Comments at USDA-FDA Joint Public Meeting (October 23, 2018), available at https://bit.ly/3c3pWoU.

meat. And at this critical stage of the technology's development, the dangers of ill-fitted (if well-intentioned) regulations are especially serious: both the technology itself and consumer understanding of that technology are rapidly developing, and regulations created today risk being out of date within a few short years, possibly even before the products become widely available. FSIS should therefore support the industry's development by favoring regulatory flexibility, and at this stage should eschew any rigid and prescriptive regime for the labeling of cultivated meat.

In considering how to regulate the labeling of cultivated meat, FSIS should take the free-speech rights of producers seriously. As discussed below, producers have the right to truthfully communicate with consumers, and consumers have the similarly protected right to *receive* information from producers. The First Amendment to the U.S. Constitution prohibits undue state interference in this flow of information, and it is critical that FSIS respect producers' and consumers' speech rights as they learn how to communicate about these innovative new products. Thus, as described more fully below, GFI agrees with the Petition's central argument against establishing new standards of identity and, more generally, that FSIS should avoid regulating labels in a manner that is overly narrow or prescriptive at this time. We also submit that the careful approach described in the Petition is required by the First Amendment.

I. The First Amendment prohibits unduly speech-restrictive regulation of the labeling and advertising of cultivated meat.

The First Amendment protects the rights of commercial speakers to communicate truthfully as well as the rights of consumers to receive information. Thus, when the government proposes to restrict truthful commercial speech (including labels and advertising), the government must demonstrate that the proposed restriction narrowly and directly advances a substantial government interest, such as preventing consumer deception. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980).

In public hearings and submissions to the agency, some commenters have advocated for FSIS to promulgate severe restrictions on how producers may describe cultivated meat, up to and including a ban on calling it "meat" entirely.[2] Some commenters have also suggested that the agency mandate inaccurate and derogatory label "disclosures" on cultivated meat products. As discussed below, each of these proposed speech restrictions would be unconstitutional. FSIS should reject these calls for anticompetitive regulation, and instead should favor a flexible approach that allows truthful and clear communication between producers and consumers.

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[2] *See, e.g.*, U.S. Cattlemen's Association, *Petition for the Imposition of Beef and Meat Labeling Requirements*, FSIS No. 18-01 (Feb. 9, 2018), at 4–6, 8–9; Comment from the National Farmers Organization, available at https://bit.ly/2H4OBy1.

A. Prohibiting the use of common names for meat and poultry products on cultivated meat labels would violate the First Amendment.

FSIS plans to regulate the inspection and labeling of cultivated meat from amenable species,[3] and FSIS's authority over such products is premised on cultivated meat's classification as a meat food product and on cultivated poultry's classification as a poultry product.[4] And these products *are* meat and poultry, produced in a new way. It is both clear and natural to describe them as such, using the same recognizable names as conventional meat and poultry products.

FSIS and common practice have established many standardized terms and common names for meat food products, such as "hamburger" or "sausage." Some such meat terms are specifically standardized in FSIS regulations,[5] while others are described in USDA's Food Standards and Labeling Policy Book or have been established by common industry and consumer usage.

Some conventional meat producers argue that FSIS should not permit cultivated meat products to be described using these terms, or indeed *any* common words or phrases used to refer to conventional meat products. Such an approach restricting the use of common meat product terms on cultivated meat products would not withstand constitutional scrutiny under *Central Hudson*, as described in detail in the Petition (at pages 8–13). It would be practically impossible, for example, to describe a sausage made from cultivated meat without using the word "sausage" itself; nor would it be feasible to identify the cultivated meat in such a sausage as porcine without using the word "pork." And forbidding a producer to call such a product a pork sausage — or worse, prohibiting *any* reference to pork or sausage — would not advance any legitimate state interest in protecting consumers from confusion. Quite the opposite: forcing producers to use awkward and unfamiliar descriptive terms would only serve to confuse, rather than inform, consumers — ultimately *hiding* from the consumers the basic nature of a product having all the expected culinary properties of pork sausage. Worse yet, hiding the product's porcine nature would be detrimental to those with religious dietary restrictions, and dangerous (possibly fatal) to some with pork allergies. Clear, readily-understood labeling is itself a consumer protection issue, reaching not just confusion but human health.

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3 *See* 21 U.S.C. § 601(w).

4 *See* USDA & FDA, Formal Agreement Between U.S. Department of Health and Human Services Food and Drug Administration and U.S. Department of Agriculture Office of Food Safety (March 7, 2019), available at https://www.fsis.usda.gov/formalagreement (asserting cultivated meat's status as a product regulated under the FMIA and PPIA).

5 *See generally* 9 C.F.R. part 319.

We further agree that a blanket ban on using existing meat terms to describe cultivated meat could not be justified by a material difference (for example, in nutrition) between a cultivated product and its conventional counterpart, because there are less restrictive means of achieving the intended purpose.[6] Several court rulings have established that blanket speech bans are strongly disfavored where corrective disclosures are a feasible alternative, because disclosures are a more narrowly tailored means of advancing any state interest in preventing consumer confusion.[7] Thus, in the case of a material difference in the product, an appropriate disclosure of that difference would more directly advance consumers' informational interest than a broad and confusing speech ban on meaty words.

Finally, regulators and courts have historically rejected analogous restrictions in food labeling — specifically, in the labeling of plant-based alternatives to conventional meat and dairy products. Unlike cultivated meat products, such plant-based products do *not* meet regulatory definitions for meat and dairy products, and some may argue that this provides a plausible basis for excluding meat and dairy terms from plant-based food labels. Yet courts have repeatedly rejected arguments for speech bans on such plant-based product labels. For example, one court recently enjoined a state law that restricted terms like "burger," "sausage," "roast," or "chorizo" on plant-based products;[8] numerous courts have dismissed arguments that soy milk and almond milk should not use the word "milk" because they do not come from cows;[9] one court recently enjoined a state enforcement action against the use of the word "butter" on a "vegan butter" product;[10] and even decades ago courts rejected similar state restrictions on use of the words "butter" or "buttery."[11] Moreover, as the Petition notes, content- and speaker-based

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6 USDA's existing standards for meat products and especially processed meat products often allow a great deal of variation, allowing for the use of different types of meat or other ingredients in varying proportions and of varying quality, fattiness, and so forth. For processed meat products, it would not be difficult for cultivated meat products to fall within the range of normal nutrition for the variety of conventional counterparts, even if some cultivated meats were to ultimately differ from conventional meats to some detectable degree.

7 *See, e.g.*, *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228, 1240 (11th Cir. 2017); *Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999).

8 *Turtle Island Foods SPC v. Soman*, 424 F. Supp. 3d 552, 573–76 (E.D. Ark. 2019) (finding state prohibition of meat terms on plant-based product labels likely unconstitutional).

9 *Painter v. Blue Diamond Growers*, 2018 WL 6720560 (9th Cir. Dec. 20, 2018); *Gitson v. Trader Joe's Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013).

10 Preliminary Injunction Order, *Miyoko's Kitchen v. Ross*, 20-cv-893 (N.D. Cal., Aug. 21, 2020), attached to this comment (finding likelihood of success in challenging ban on using word "butter" on plant-based buttery spread).

11 *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645, 651–52 (S.D. Ohio 1989); *Anderson, Clayton & Co. v. Wash. St. Dept. of Agric.*, 402 F. Supp. 1253, 1257–58 (W.D. Wash 1975).

restrictions have recently received heightened scrutiny from the Supreme Court,[12] and unique restrictions on producers of cultivated meat (but not conventional meat) would likely be deemed to be both content- and speaker-based. Under this level of intense scrutiny, bans of natural consumer-friendly language do not serve any substantial state interest and are presumptively unconstitutional.[13] FSIS should therefore respect the First Amendment and decline to protect conventional meat producers from the free market by censoring their competitors.

B. Mandating specific terms or disclosures would be premature at this stage and would unduly restrict speech.

Speech mandates as well as speech restrictions raise serious First Amendment free speech concerns. We therefore agree with the Petition that a regulation mandating particular speech on cultivated meat labels would be premature and unduly restrictive. For just as the technologies for producing cultivated meat are rapidly developing, so too is the language that producers and consumers use to describe cultivated meat products.[14] No universal descriptor or nomenclature for these products has been agreed upon by the companies that are developing cultivated meat, nor have consumers settled on a universally understood term for these products (indeed, many consumers have yet to learn of the possibility of such products). All of this is likely to change quickly when cultivated meat products become widely available and consumers are more broadly informed about this method of producing meat. Only then are consumers and producers likely to settle on common language for referring to these products.

Producers of cultivated meat are in the best position to explain their new products to consumers and society, and FSIS should not attempt to dictate the terms of this conversation before it runs its natural course. Indeed, such an attempt would be inconsistent with FSIS's historical regulation of common food names — FSIS does not *create* consumer understanding by inventing new food names, but rather FSIS *codifies* consumer understanding by setting standards for foods with established names. We are unaware of a single standardized meat product name (either in regulations or the Labeling Policy Book) that is the result of top-down prescription from the government, rather than the bottom-up recognition of a term consumers and producers already use.

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12 *Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653, 2664–65, 2667 (2011).

13 *Id.*; *see also Ocheesee Creamery*, 851 F.3d at 1235 n.7 (striking down state label restriction on "skim milk" under intermediate scrutiny, while mentioning the possibility that it could be subjected to heightened scrutiny under Sorrell).

14 For example, GFI and some cultivated meat companies use the term "cultivated meat" in direct reference to the process for growing the meat, while the Petition and other companies use the term "cell-based meat" in reference to the starting material from which the meat is grown. But the term that consumers and society ultimately adopt might be either or neither of these.

For this reason, we concur with the Petition's recommendation that no specific mandated language or standards be prescribed at this time. Without an actual market for cultivated meat, the agency would be trying to regulate in the dark. A premature agency mandate cannot hope to accurately capture consumers' and producers' eventual nomenclature for products not yet available. Instead, mandating specific language or disclosures creates the risk that the prescribed language will be outdated before the products are even on the market, serving no consumer protection function at all.[15]

In light of these practical concerns, prescribing terms or disclosures that are neither used nor understood by producers or consumers raises serious First Amendment concerns. Government regulations of commercial speech must be justified by a substantial state interest, often protecting consumers while ensuring they get necessary information. Speech regulation governing a product not on the market serves no such interest. And although the government faces a somewhat lower burden in justifying mandatory commercial factual *disclosures* (as opposed to restrictions), this lesser degree of scrutiny only applies when the disclosures are truly *factual* and uncontroversial in nature.[16] But given the unsettled state of the nomenclature around cultivated meat products, any mandated labeling terminology at this early stage would inevitably be controversial. And some terms — such as the "lab-grown" moniker favored by some opponents of this technology — are both factually inaccurate[17] *and* highly controversial.

Thus, at a bare minimum, any mandated language or disclosures on cultivated meat labels would need to be well-understood and widely accepted, as well as factually accurate and not derogatory towards the product. And until producers and consumers begin to use common language for these products, no single mandated term would be

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15 Further, inaccurate regulations can persist for many years by sheer inertia. Consider the wide variety of Italian noodles that consumers today call "pasta." FDA currently mandates a standard of identity for these products under the misnomer "macaroni products," owing to a regulation (21 C.F.R. § 139.110) from 1944. But "macaroni" today is well-understood to refer to small tubular pasta varieties, usually elbow-shaped, and not to other types of pasta (which some Americans may have generally called "macaroni" a century ago). Yet this outdated regulation persists, requiring most Italian pastas (be they rotini, penne, or fettuccine) to all bear the same awkward "macaroni product" moniker in every American grocery store.

16 *See American Meat Inst. v. USDA*, 760 F.3d 18, 27 (D.C. Cir. 2014) (en banc) (upholding USDA's regulation requiring disclosure of the uncontroversial fact of meat's country-of-origin).

17 The phrase "lab-grown" refers to an experimental setting (a laboratory) where research occurs. But cultivated meat production for the market will involve standardized non-experimental processes in a regulated food production facility. Thus, cultivated meat will not be any more "lab-grown" than any other product of modern food technology on the market today. As Finless Foods' founder Mike Selden noted at the USDA-FDA joint public meeting on October 24, 2018, products like beer are also prototyped in a lab, and thus if cultivated meat is "lab-grown meat," "then beer is lab-grown beer." USDA-FDA Joint Public Meeting Day 2 Morning Session, Transcript at 17, available at https://bit.ly/3hDP1Ie.

appropriate. FSIS should not therefore attempt to require any specific language at this early stage. Instead, as described next, the agency should review any proposed labels on a case-by-case basis for factual accuracy and clarity.

C. The First Amendment requires that FSIS permit voluntary disclosures or "credence claims" in cultivated meat labeling.

Under the USDA/FDA joint framework announced in 2019, cultivated meat[18] and poultry producers will be required to submit their proposed labels to FSIS for approval. This regulatory step allows FSIS to ensure that each individual label is truthful and not misleading to consumers. FSIS's case-by-case review obviates the need for it to formulate a one-size-fits-all labeling regime before any products are on the market. In First Amendment terms, existing FSIS review greatly undermines any argument that an overly restrictive labeling regulation would be narrowly tailored and necessary to protect consumers. We further note that FSIS's label review process for cultivated meat must *itself* carefully respect commercial free speech by allowing producers to voluntarily advertise the nature and benefits of their products.

This is especially important because once cultivated meat products are ready for sale to consumers, they will be premium products initially, with a price point significantly above that of conventional meat. Accordingly, producers will need to go to greater lengths to communicate the advantages of their products to consumers, and labels will be a key channel for that direct-to-consumer communication. Unduly restrictive label regulations — including any limits on specific voluntary claims — could threaten the ability of producers to communicate clearly with consumers in this critical forum, which could itself undermine consumers' First Amendment interest in receiving information.

For this reason as well, we agree with the Petition's recommendation that FSIS adopt a labeling approach that does not overly restrict speech and respects First Amendment commercial speech protections. In this light, any regulations must leave ample room for producers to make voluntary or "credence claim" disclosures about their production processes and benefits of their products. Under well-settled First Amendment principles, FSIS may not restrict such voluntary communications without substantial justification (e.g., if a claim is false or misleading).[19] Some producers may wish to make voluntary labeling statements or credence claims explaining the benefits of the technology to consumers, including (for example) positive food safety aspects, environmental aspects, or animal welfare aspects of their products and production methods. And given the important interest producers have in explaining these novel

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18 From amenable species under 21 U.S.C. § 601(w).

19 More generally, FSIS would need to show that a commercial speech restriction directly advances a demonstrated substantial interest, and that it is narrowly drawn to that end. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980).

products to consumers at the critical initial stage of their release to market, FSIS should take extra care to avoid unduly burdening the major consumer-facing communication under its purview — the product label.

II. Technical aspects are still under development, which also counsels against premature regulation.

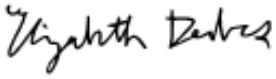
The Petition notes the possibility that some cultivated meat products may have compositional differences from conventional meat products, though this is far from clear. If there are material compositional differences between some cultivated meat products and their counterparts, the nature of any mandatory disclosure tailored to those differences would necessarily turn on the nature of those differences. As noted in the Petition, FSIS will be able to draw on information collected by FDA during the pre-market safety review in order to determine on a case-by-case basis whether to require additional disclosures tailored to such differences.

There are other technical uncertainties about the products that will eventually be approved for the U.S. market, as a number of cultivated meat researchers and companies are developing a variety of different methods for cultivated meat production. The range of production methods ultimately approved by federal regulators may use a variety of growth media formulations from different sources; some may use scaffolding that remains in the final product; some may make use of genetic engineering, while others may not; and some may blend cultivated meat together with plant-based proteins or fats in the same product. This diversity of possible production methods and products counsels against a premature one-size-fits-all regulation for labeling such products. For this reason too, we agree that FSIS should not promulgate requirements for mandatory disclosures or qualifiers at this time, and should await the information necessary to adequately tailor any mandated disclosures to approved technologies and products. This careful approach would accord due respect to producers' commercial free speech rights.

Conclusion

Restrictive speech regulations for cultivated meat would serve no consumer protection interest and would violate the First Amendment, all while suppressing innovation and free market competition. We respectfully urge FSIS to take the cautious approach outlined above in addressing this fast-developing technology, because such an approach is the best way to respect the vital free-speech interests of both producers and consumers. We thank FSIS for the opportunity to comment on the Petition. Please contact us if we can provide any further information.

Respectfully,



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