ANIMAL LEGAL DEFENSE FUND EST 1979

525 East Cotati Avenue
Cotati, California 94931

T 707.795.2533
F 707.795.7280

info@aldf.org
aldf.org

December 19, 2018

Juanita Yates
Public Affairs Specialist
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Docket Clerk
Food Safety and Inspection Service
United Stated Department of Agriculture
1400 Independence Avenue SW, Mailstop 3758, Rm 6065
Washington, DC 20250-3700

Submitted electronically via regulations.gov

Re: ALDF Comments Regarding the Regulation of Cell Culture Technology to Develop Products Derived from Livestock and Poultry: Docket ID FSIS-2018-0036

Dear Ms. Yates and Ms. Smith,

On behalf of the Animal Legal Defense Fund ("ALDF") and the undersigned organizations, we write to provide comments regarding the use of cell culture technology to develop products derived from livestock and poultry. We write in response to the Food and Drug Administration ("FDA") / Food Safety and Inspection Service ("FSIS") Joint Public Meeting held on October 23–24, 2018. ALDF also submitted comments to FDA in response to its public meeting on foods produced using animal cell culture technology ("FDA Comment"), which we have included as Appendix A for reference.[1] FDA and USDA have since announced a dual jurisdiction approach that appears to assert FDA jurisdiction over pre-harvest production and USDA jurisdiction over cell harvest and product labeling.[2] We appreciate that FDA and USDA ("the Agencies") are committed

[1] A similar but unique group of organizations signed the FDA Comment. We include Appendix A on behalf of the present group of animal protection organizations to the extent that it is referenced and relied upon herein.

[2] Press Release, USDA, 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),

to moving forward and collaboratively identifying an efficient pathway to market for these exciting products.

Using cell culture technology to produce meat and poultry products makes possible a desperately needed paradigm shift in how we produce the animal products that will feed an increasing human population. These transformative innovations promise to end the suffering endured by billions of animals in conventional animal agriculture, while simultaneously strengthening the safety and resilience of the U.S. food system. Factory farming subjects animals to torturous (but common) husbandry practices including intensive confinement, routine mutilations, and living in filthy and disease-inducing conditions. It also causes severe environmental degradation and endangers public health.[3] Using cell culturing techniques instead of live animals to produce meat and poultry products promises to drastically reduce these environmental impacts and public health risks, and would unhitch our food system from the animal cruelty upon which it currently depends.

Because of the animal suffering, environmental impacts, and human health issues associated with conventional, factory-farmed meat and poultry, consumers are increasingly seeking out alternatives. This growing consumer demand is evidenced by the rapid increase in purchases of plant-based meat and poultry alternatives in recent years.[4] Because slaughter-free meat and poultry products[5] are made from animal cells, they could offer the same structural, chemical, and functional properties as the meat and poultry consumers are accustomed to, without the many negative attributes of conventional factory-farmed products.

Given the transformative potential of these new products and the growing consumer demand for better options, it is critical that the FDA and FSIS ensure a level playing field that does not favor entrenched livestock and meat interests at the expense of innovation and consumer choice. Thus far, the reaction from the livestock and meat and poultry industries to this new innovation has largely been hostile and protectionist. Some have proffered irrational, counter-productive, and potentially dangerous suggestions as to the approach and actions the Agencies should take towards these new

---

https://www.usda.gov/media/press-releases/2018/11/16/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb (last visited Dec. 17, 2018).

[3] *E.g.*, American Society for the Prevention of Cruelty to Animals, *Factory Farming*, https://www.aspca.org/animal-cruelty/farm-animal-welfare (last visited Dec. 10, 2018); Gidon Eshel et al., *Land, Irrigation Water, Greenhouse Gas, and Reactive Nitrogen Burdens of Meat, Eggs, and Dairy Production in the United States*, 111(33) PNAS 11,996 (Aug. 2014); Gowri Koneswaran & Danielle Nierenberg, *Global Farm Animal Production and Global Warming: Impacting and Mitigating Climate Change*, 116(5) ENV. HEALTH PERSPECTIVE 578 (May 2008); Mary D. Barton, *Impact of Antibiotic Use in the Swine Industry*, 19 CURRENT OPINION MICROBIOLOGY 9 (June 2014).

[4] As just one of many supporting data points, the Plant Based Food Association released data in July 2018, showing a 24% growth in plant-based meat sales from last year. See PBFA, *Plant-Based Food Sales Grow 20 Percent* (July 30, 2018), https://plantbasedfoods.org/wp-content/uploads/2018/07/PBFA-Release-on-Nielsen-Data-7.30.18.pdf (last visited Dec. 10, 2018).

[5] The FDA Comment, included at Appendix A, used the term "clean meat" while recognizing the dynamic conversation around appropriate terminology for these new products. Here we use "conventional" and "slaughter-free" to refer to meat and poultry produced conventionally versus from cell culture technology, respectively. From the perspective of consumers concerned about farmed animal welfare, we believe this accurately describes the most important attribute of these new products.

products, in what must be understood (and rejected) as attempts to stifle competition and consumer choice.

The Agencies must not succumb to these one-sided interests by erecting unnecessary hurdles to market entry or by imposing disproportionate or harmful labeling requirements.

I. The Agencies' Announcement of Shared Jurisdiction

We commend the Agencies for working diligently to establish a regulatory framework that will identify an efficient pathway to market and create much-needed regulatory certainty for producers using animal cell culture technology.[6] We understand from the joint statement that FDA will be in charge of making any needed pre-market safety assessments of these products, which we fully support given FDA's experience with foods and food additives produced using cell culture technology.

The proposed dual jurisdiction arrangement does raise concerns, however, about potentially duplicative oversight that would be inefficient for the Agencies and burdensome for producers, with no attendant improvement in food safety. ALDF has interpreted the Agencies to say that FDA will have jurisdiction up until, but not including, cell harvest, with USDA oversight starting at cell harvest and continuing through processing and labeling.[7] Assuming we have understood the Agencies correctly, it seems likely that this will require animal cell culture production facilities to have both FDA and FSIS inspections and oversight, as the products could be harvested from the same bioreactors that are used to culture and grow the cells. Unless the Agencies have a rational food safety-related justification for requiring facilities to undergo *both* FDA and FSIS inspections and reporting for the same production process, this proposal should be streamlined to allow FDA to inspect and oversee the entire production process, and FSIS to oversee the processing of raw material into final products.

II. Food Safety Considerations

The first and most important role for the Agencies is to ensure the safety of these new food products in a transparent and trustworthy manner before they enter the marketplace. This is an important prerequisite to building the consumer confidence that will make widespread market adoption of these transformative products possible. We commend and agree with FDA's

---

[6] As an initial matter, FSIS must agree that these products are "meat food product" and "poultry" as defined under the FMIA and PPIA, respectively, given that such a construction is a prerequisite to the agency having any authority to regulate these products. FSIS may not later try and limit or prohibit the use of these and other similar terms as used on slaughter-free products without contradicting this threshold jurisdictional determination. Additionally, we note that FDA will continue to have exclusive jurisdiction over all non-amenable, non-poultry species from which slaughter-free varieties are produced. This includes all foods from aquatic species (other than siluriformes), and any terrestrial species that is not an amenable species under the FMIA. FDA and FSIS must ensure consistency in how they regulate food product labeling as to these other foods produced using these same cell culturing methods.

[7] We note that an alternative interpretation exists where FDA would oversee all bioreactor operations, including cell harvest, and USDA would oversee post-bioreactor processing and labeling. Such an interpretation could alleviate the dual jurisdiction concern raised above, and we encourage the Agencies to take this approach.

commitment to make any needed pre-market safety assessment of products produced using animal cell culture technology.[8] As expressed in the FDA Comment, FDA should build off its considerable experience with other cell culture technology applications, where consumer and food safety has already been well established, to establish and communicate the safety of these new food products.

Unfortunately, at the October 23–24, 2018 Joint Public Meeting, some commenters offered misleading, fear-based arguments as to these products' safety or alleged lack thereof.[9] These comments highlight the importance of an affirmative safety determination by FDA and FSIS, communicated to the general public in an open manner with understandable, non-technical language. As with most transformative new products, but especially so with food, some degree of consumer reticence can be expected—which makes leadership from the Agencies even more important. FDA should communicate to the public its substantial track record of ensuring the safe production of food with cell culture technology, and that these new products should not be feared. And once commercial production of these products begins, FSIS will have an important role in ensuring public confidence in these products through its inspection process and approval of wholesomeness.

A. Agency Oversight Must Be Fair and Based on the Technical Details of This Production Method

The same general principles expressed in the FDA Comment, with respect to FDA food safety oversight, apply to FSIS's asserted oversight of cell harvest and processing: Regulations should be fair and specifically tailored to the technical details of this new production method, not rigidly based on inapposite regulations pertaining to the unique food safety concerns presented by slaughtering live animals—such as animal disease, infected abscesses, and fecal matter. Indeed, FSIS's role in ensuring the safe harvest and processing of slaughter-free meat and poultry should be considerably easier than its responsibility to do the same with products derived from the slaughter and processing of live animals.

The Agencies should ensure food safety in the least burdensome way possible while also instilling consumer confidence in the process. This will require transparency and clearly articulated safety assurances by both FDA and FSIS. The Agencies' Hazard Analysis and Critical Control Points (HACCP) principles, and FDA's Hazard Analysis and Risk-Based Preventive Controls, should guide the development of an appropriate food safety framework for these new products that consumers can trust.[10]

---

[8] Here we incorporate and highlight our points in the FDA Comment that any safety assessment should not require or rely on animal tests, which are unreliable and poorly predictive of human health outcomes. FDA Comment at 3–4.

[9] For example, one commenter baselessly compared animal cell culture production to cancerous lesions.

[10] USDA, HACCP Seven Principles (Mar. 15, 2016), https://www.fsis.usda.gov/wps/wcm/connect/9bef6a34-d7ef-441e-8478-f431aee441cf/16_IM_HACCP_Principles.pdf?MOD=AJPERES (last visited Dec. 10, 2018); FDA, Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (Jan. 2018), https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517610.pdf (last visited Dec. 10, 2018).

B. Frequency of Inspections

Decisions as to the type and frequency of slaughter-free meat and poultry production inspections should be based on the technical details of particular cell culturing systems. The FDA appropriately takes the position that it "inspects food facilities on a varying schedule based upon the risk level of the product."[11] Existing cell culture applications likely have inspection regimes in place that could be transferable to this context. For example, a HACCP plan already exists for the production of spirulina as a direct food additive through cell culturing.[12] It bears to reason that lessons learned in that and other cell culture applications (such as mycoprotein and yogurt production) will inform what critical control points and inspection schedules might be appropriate for these cell culture applications.

Some livestock producers and conventional meat and poultry interest groups have demanded that inspection of slaughter-free meat and poultry production be essentially identical to that administered by FSIS in conventional slaughter and processing plants.[13] The only support for such a demand appears to be that existing producers think anything else would be unfair, since these new products will ultimately compete with them in the marketplace. This is not a valid justification for imposing inspection requirements different than what are actually necessary to ensure food safety. Given the drastically different contamination pathways involved, a parity requirement would be irrational and unlikely to result in effective and efficient food safety oversight. Instead, the Agencies should look to the FDA's well-established hazard assessments and control points already in place for existing foods and food additives produced using cell culture technology.[14] Unless FDA and FSIS identify unique food safety risks with animal cell culture applications compared with existing applications, no additional inspection should be required.

III. Labeling

The importance of informative, accurate labeling is second only to safety in the public roll-out of these transformative products. FSIS, as the agency that has claimed sole jurisdiction over slaughter-free meat and poultry labeling, must fulfill its statutory duty under the FMIA and PPIA to ensure that labeling is truthful and not misleading, without imposing requirements that unnecessarily thwart consumer adoption. FSIS should also be mindful of the nascent stage these new products are in and

---

[11] FDA, *How to Start a Food Business* (updated Sept. 17, 2018), https://www.fda.gov/food/resourcesforyou/industry/ucm322302.htm#Inspiections (last visited Dec. 10, 2018).
[12] *E.g.*, Nutra Ingredients, *Earthrise Obtains HACCP for Spirulina* (Nov. 9, 2009), https://www.nutraingredients-usa.com/Article/2009/11/09/Earthrise-obtains-HACCP-for-spirulina# (last visited Dec. 10, 2018).
[13] For example, the Illinois Beef Association asserts that "Under USDA-FSIS oversight, any product purporting to be a meat food product will be subject to the same inspection procedures as traditional products." https://www.regulations.gov/document?D=FSIS-2018-0036-0111 (last visited Dec. 10, 2018).
[14] *See* Transcript of July 12 FDA Meeting at 23 ("For example, FDA has evaluated a variety of foods produced by cell culture, including microbial products such as probiotics, algal products such as spirulina and fungal products or the mycoprotein products as well." (statement by Dr. Susan T. Mayne, Director of the Center for Food Safety and Applied Nutrition)); 83 Fed. Reg. 28,238, 28,239 ("Currently, FDA evaluates microbial, algal, and fungal cells generated by large-scale culture and used as direct food ingredients . . . .").

the public's lack of familiarity with them, and avoid premature labeling determinations that could hamper innovation and consumer choice, or worse, *create* consumer confusion.

FSIS must facilitate informative labeling that communicates to consumers what these products are—meat, made without slaughtering animals. Protecting conventional meat products' market share and communicating their claimed superiority over these news products, by contrast, are *not* part of FSIS's mandate, and should play no role in the Agencies' decision making.

We applaud the calls for transparency that were expressed at the Joint Public Meeting from slaughter-free and conventional producers alike. ALDF and the undersigned have long advocated for transparent and informative labeling of meat and poultry products, and our position remains unchanged: truthful, informative labeling is necessary to ensure that consumers are empowered to purchase products that comport with their ethics and expectations, which are increasingly informed by animal welfare, environmental sustainability, and public health concerns.[15]

A. FSIS Must Oversee Product Labeling Thoughtfully and Fairly

FSIS must oversee the labeling of slaughter-free meat and poultry products thoughtfully and fairly, and must recognize that heavy-handed regulation could harm these products' marketability and consumers' ability to make informed purchasing decisions.

First, it would be premature to establish any particular standardized terminology for slaughter-free meat and poultry products at this early stage, when the actual attributes of the products are as of yet unknown with any certainty, and when public awareness of these products is close to nonexistent. Effective marketing will be of central importance to these new companies, and FSIS should allow producers the flexibility to experiment with how best to describe their products on labels. Codifying a single qualifier (such as "cell-based" or "cultured"), by contrast, would deny this new food sector the opportunity to engage with consumers to reach consensus about what terminology will best convey slaughter-free products' attributes.

Second, the suggested labeling requirements proposed by some livestock interests and conventional meat and poultry groups are attempts to disparage and handicap these new products and protect existing market share. Under no circumstance may FSIS require slaughter-free meat and poultry producers to label their products with monikers such as "fake," "imitation," "synthetic," or "lab-grown." At best, these terms are not informative; at worst, they are inaccurate and misleading.[16] Likewise, demands that slaughter-free meat and poultry companies be barred from using common terms that consumers recognize—like "chicken" or "beef"—on their labels are inappropriate and even

[15] *See* Petition No. 13-03, ALDF Petition Seeking Mandatory Meat and Poultry Labeling to Prevent the Sale of Misbranded Products (June 2013); ALDF Petition to Require Foie Gras Labeling (both available at https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/petitions (last visited Dec. 10, 2018)).

[16] For example, "lab-grown" would be patently misleading as slaughter-free meat and poultry will not be produced in a laboratory setting. As one producer explained during the Joint Public Meeting, laboratory work on slaughter-free products is limited to the testing and development phase in the same manner that, for example, a new Doritos™ flavor would be tested before marketization. Full-scale production will take place in manufacturing facilities much like those used to produce other cultured products. If slaughter-free products must be labeled as "lab-grown," then any product that goes through a lab-based testing phase would also have to bear such labeling.

dangerous.[17] The Agencies should reject these poorly-considered and self-serving demands, and instead focus on ensuring that labels include accurate and helpful information that will empower consumers who want more protein choices.

B. Responses to the Agencies' Labeling Questions

a. Should the methods by which animal cell cultured products are produced (*i.e.*, the culturing process) be considered required information for purposes of labeling? If so, what factors should be considered in accurately describing the production methods?

As detailed below, any production process labeling requirements should adhere to two considerations: equity and flexibility.

i. Equity

Consumers should be able to distinguish slaughter-free from conventional meat and poultry varieties, but all producers have a responsibility to label their products honestly by disclosing product attributes that consumers care deeply about. In the past, FSIS has taken the position that producers do not need to affirmatively disclose a production practice unless it affects the product "in a manner that is not obvious to consumers in the absence of labeling," such as when a product is irradiated.[18] To date, FSIS has not required any affirmative labeling of animal husbandry practices, despite growing consumer interest in how animals are raised for food. If FSIS now believes that production method is material to consumer purchasing decisions, such that slaughter-free products must disclose it on labels, so too must conventional products disclose their own production methods—animal confinement, administration of antibiotics, et cetera—that ample evidence demonstrates are subjects of significant consumer concern.[19]

The Agencies were told by some livestock and conventional producers at the Joint Public Meeting that consumers know exactly what they are getting when they purchase those producers' meat and poultry products. Nothing could be further from the truth. Evidence abounds that most consumers are out of touch with modern agriculture and remain uninformed about the industrial animal production and slaughter practices that are used to produce their food,[20] despite growing interest and

[17] This approach is exemplified by the U.S. Cattlemen's Association petition to FSIS. Docket ID FSIS-2018-0016, USCA Petition for the Imposition of Beef and Meat Labeling Requirements: To Exclude Products Not Derived Directly from Animals Raised and Slaughtered from the Definition of "Beef" and "Meat" (Feb. 9, 2018), https://www.fsis.usda.gov/wps/wcm/connect/e4749f95-e79a-4ba5-883b-394c8bdc97a3/18-01-Petition-US-Cattlement-Association020918.pdf?MOD=AJPERES (last visited Dec. 10, 2018).

[18] *See* Irradiation of Meat Food Products; Final Rule, 64 Fed. Reg. 72,149, 72,158, 72,163.

[19] *See, e.g.*, Animal Welfare Institute, *Consumer Perceptions of Farm Animal Welfare* (last updated Aug. 2018), https://awionline.org/sites/default/files/uploads/documents/fa-consumer_perceptionsoffarmwelfare_-112511.pdf (last visited Dec. 10, 2018) (compilation of consumer research in this area); Alice Hancock, *Younger Consumers Drive Shift to Ethical Products*, FINANCIAL TIMES (Dec. 22, 2017), https://www.ft.com/content/8b08bf4c-e5a0-11e7-8b99-0191e45377ec (last visited Nov. 29, 2018).

[20] "Unfortunately, a majority of today's consumers are at least three generations removed from agriculture, are not literate about where food comes from and how it is produced." Caitlin Dewey, *The Surprising Number of American Adults Who Think Chocolate Milk Comes from Brown Cows*, WASH. POST (June 15, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/06/15/seven-percent-of-americans-think-chocolate-

concern in the topic. Most consumer do not know, for example, that the animals used in industrial meat and poultry production (1) are forced to live in enclosures so small they can barely move; (2) are routinely administered antibiotics to prevent disease and enable them to survive and grow quickly in filthy and crowded housing; (3) have been bred to maximize production at the expense of welfare; and (4) are often never allowed access to the outdoors and have essentially no opportunities to engage in their natural behaviors, among many other gruesome realities.[21]

Furthermore, most consumers are unaware of the horrors that occur each and every day at slaughter plants across the United States, such as chickens being scalded alive, the slaughter and processing of pigs too sick or weak to walk, or the prevalence of disease and injury in slaughtered animals. Surveys reliably demonstrate that consumers care about all of the above and more; yet, they are intentionally kept in the dark about the true practices of industrial animal agriculture production.[22] The Administrative Procedure Act prohibits arbitrary and capricious agency action.[23] It would be the height of arbitrariness to require production method labeling disclosures on safer, more humane, less environmentally damaging products without requiring the same for crueler, more dangerous, factory-farmed ones.

However, given the spirit of transparency infusing the present conversation, FSIS should take the opportunity to ensure that consumers are empowered to make informed purchasing decisions related to production methods across the board, not just for slaughter-free varieties. For example, FSIS should revisit ALDF's pending petition, submitted in 2013, to establish mandatory labeling to disclose routine antibiotic use in animals used to produce meat and poultry products.[24] For FSIS to reject this and other calls for truthful labeling disclosures on conventional products, where consumer confusion and interest is prevalent, yet require the affirmative disclosure of slaughter-free production practices, would be an unreasonable double standard that would unfairly advantage one industry over another and undermine consumer choice.

ii. Flexibility

If any type of affirmative disclosure of production methods is required for slaughter-free products, it should not be a one-size-fits-all mandate that requires disclosure in a certain way—in the statement of identity for example. As a practical matter, these new products will have every incentive to distinguish themselves in honest and transparent ways. That leading innovators in the field have

---

milk-comes-from-brown-cows-and-thats-not-even-the-scary-part/?utm_term=.e4b09468dd17 (last visited Dec. 10, 2018) (quoting a white paper by the National Institute for Animal Agriculture).

[21] *See, e.g.*, Animal Welfare Institute, *Consumer Perceptions of Farm Animal Welfare* (last updated Aug. 2018), https://awionline.org/sites/default/files/uploads/documents/fa-consumer_perceptionsoffarmwelfare_-112511.pdf (last visited Dec. 10, 2018) (compilation of consumer research in this area).

[22] The conventional meat and poultry industry has clearly shown its aversion to transparency by aggressively pushing for "ag-gag" laws that prohibit and criminalize the collection and dissemination of information about how animals are raised. *See* ALDF, *Ag-Gag Laws*, https://aldf.org/issue/ag-gag/ (last visited Dec. 11. 2018).

[23] 5 U.S.C. § 706 ("The reviewing court shall…hold unlawful and set aside agency action, findings, and conclusions found to be…arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law….").

[24] Petition No. 13-03, ALDF Petition Seeking Mandatory Meat and Poultry Labeling to Prevent the Sale of Misbranded Products (June 2013).

embraced qualifying nomenclature such as "cell-based"[25] and "cultured"[26] is evidence of this. But as FSIS reviews pre-market label submissions from these companies, it must keep in mind that there is simply no reliable data on what exactly would be misleading to the average consumer, who presently knows only that meat and poultry comes from slaughtering live animals. Does "cell-based" truly communicate to consumers the relevant differences among plant-based meats, slaughter-based, and slaughter-free varieties?[27] This uncertainty counsels in favor of a cautious, straightforward approach. Consumers should be able to tell from a meat or poultry product's label whether it comes from a slaughtered animal or not. But beyond this, FSIS should work with producers to develop guidance that will establish needed regulatory certainty while allowing for the flexibility essential to these early stages of market development.

a. Should standards of identity or criteria for statements of identity be established for these products to ensure that products names are truthful, not misleading, and sufficiently differentiate cell cultured products from traditional products?

No new Standards of Identity (SOIs) or criteria for statements of identity are needed to ensure accurate labeling of slaughter-free meat and poultry products. SOIs are outdated and cumbersome, as FDA itself has acknowledged, calling the SOI standard-making process "unwieldy and time-consuming."[28] The inflexibility and specificity of SOIs is particularly unsuited to a new and developing field of food production as we see here. Instead, existing regulations and FSIS's premarket labeling approval process are sufficient to ensure that slaughter-free product labeling will not be misleading.

With respect to standardized terms, proposals such as the U.S. Cattlemen's Association petition to USDA for the imposition of beef and meat labeling rules that exclude products not derived directly from animals raised and slaughtered[29] are misguided and would make truthful labeling of these new meat and poultry products impossible. The companies developing slaughter-free varieties report that their products will be structurally, chemically, and functionally indistinguishable from existing products. To prohibit a slaughter-free hamburger patty, for example, from identifying itself as "beef," when it is in fact made of beef (but didn't come from an "animal raised and slaughtered"), would only serve to confuse consumers, and could also pose a significant food allergy risk as discussed below.

With respect to the use of other standardized terms, such as "sausage" or "breaded" poultry products, slaughter-free meat and poultry varieties should be treated as falling within the definitions

[25] *Meat Institute, Memphis Meats Tell While House Both FDA and USDA Have Roles in Regulating Cell-Based Meat and Poultry Products*, NAMI (Aug. 23, 2018), https://www.meatinstitute.org/index.php?ht=display/ArticleDetails/i/148187/pid/206 (last visited Dec. 10, 2018).

[26] Some producers have embraced "cultured" as an appropriate qualifier, while others have rejected it as potentially misleading to consumers.

[27] As one commenter noted at the Joint Public Meeting, many people in the U.S. do not have an understanding of what a "cell" even is in a biological sense.

[28] FDA Consumer Health Information, *FDA's Standards for High Quality Foods* (June 18, 2007).

[29] USCA Petition, *supra* note 17.

of "meat food product" and "poultry product."[30] This will ensure that these new products are able to identify themselves to consumers based on the functional attributes that matter to consumers. Blanket bans on standardized or common and usual names would not ensure truthful labeling and would hamper the marketability of these transformative products, with no attendant benefit to consumers.

b. Should the source of the animal cell (*i.e.*, the species from which the cell line was initiated) be considered required information for the purposes of labeling?

ALDF and the undersigned agree that the source species of the cell line used to produce a meat or poultry product is an essential element to safe and truthful labeling, particularly if the products are structurally, chemically, and functionally indistinguishable from conventional ones.

First, consumers look for familiar descriptors to help them understand the nature of a product. For example, a slaughter-free chicken product will have the same organoleptic and functional qualities as conventional chicken, according to those who are producing and have tried it. A failure to disclose that the product is "chicken" would very likely confuse consumers and artificially reduce consumer choice by obscuring the nature of the product.

Second, and very importantly, consumers with certain food allergies must be able to easily identify potential allergens that they must avoid. There is every reason to believe that the proteins responsible for allergenic responses in humans from conventional meat and poultry will also be present in slaughter-free varieties of the same products. For example, a consumer with a catfish allergy needs to know that slaughter-free catfish *is catfish* in order to avoid a potentially life threatening allergic reaction. Any statement of identity that fails to identify the source species would fail to provide life-saving information to such a consumer.[31]

c. What factors should be considered in potentially allowing health, safety, and other claims in the marketing of animal cell culture products?

Slaughter-free varieties of meat and poultry products are being developed *precisely because* of their positive attributes—no animal suffering, reduced environmental impacts, et cetera. These types of claims should be reviewed as "special statements and claims" under FSIS regulations and approved where the producer can offer sufficient support, in the same way that the agency currently assesses affirmative health, safety, environmental, or animal welfare labeling claims conventional producers wish to make.[32]

---

[30] 9 C.F.R. § 301.2 (meat food product); 9 C.F.R. § 381.1 (poultry product). As noted above, these products *must* meet these threshold definitions for FSIS to have the authority to regulate here.

[31] While allergenic responses to various land-based meat and poultry products are less common, they do exist, and are on the rise. *See* Corey Whelan, *Do You Have a Chicken Allergy?*, HEALTH LINE (May 4, 2018), https://www.healthline.com/health/chicken-allergy#symptoms (last visited Dec. 10, 2018); Maryn McKenna, *Why So Many People Are Becoming Allergic to Meat*, CNN (Dec. 11. 2018), https://www.cnn.com/2018/12/11/health/tick-bites-meat-allergy-intl-partner/ (last visited Dec. 11, 2018) (discussing the rise in alpha-gal allergy (or "mammalian meat allergy") caused by a certain tick species).

[32] 9 C.F.R. § 412.1(e). While the review process for "special statements and claims" is appropriate to ensure that slaughter-free products are not misleadingly labeled, we note that FSIS is failing to adequately protect consumers from misleading animal raising claims made by conventional meat and poultry producers. FSIS's current Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label

As discussed in the FDA Comment, one specific concern we have is the use of Fetal Bovine Serum (FBS) as a growth media for cell-cultured products. To be clear, ALDF knows of no producer who plans to use FBS or any other serum-based growth media for commercial production; thus, we hope this is a moot issue. But in the unlikely event that a slaughter-free product is produced with FBS or other serum-based media, such producers should not be allowed to represent that the product is "humane" or "slaughter-free." FBS is harvested from the developed fetuses of cows found to be pregnant at slaughter. The fetal blood is collected via cardiac puncture, without any form of anesthesia or desensitization.[33] A consumer purchasing these new products believing they are not supporting the animal slaughter industry would be patently deceived by a failure to disclose the use of serum-based media on a product that otherwise positions itself as humane or slaughter-free.

IV. Conclusion

We commend FDA's and FSIS's efforts to develop an efficient regulatory pathway to market for these transformative products. Agency regulation should be fair, transparent, and clearly explained to the general public, without imposing unnecessary inspection or labeling requirements. Consumers should be able to distinguish slaughter-free products from their conventional counterparts, but rigid and premature labeling requirements would stifle innovation and could actually cause consumer confusion. Slaughter-free products must be able to use terminology that consumers are familiar with and that convey important product attributes such as functionality and allergenicity.

Respectfully,

Animal Legal Defense Fund
Aquatic Animal Law Initiative
Compassion Over Killing
Compassion in World Farming
Farm Forward
Mercy For Animals
The Humane League

Submission effectively renders any and all such claims meaningless by failing to establish uniform baseline standards. Instead, FSIS has allowed producers to use terms like "humane" and "free-range" based on their own interpretations and internal policies, which leads to confusion among consumers who care deeply about these important product attributes.

[33] Carlos E. Jochems et al, *The Use of Fetal Bovine Serum: Ethical or Scientific Problem?*, 30(2) ALTERN. LAB ANIM. 219 (Mar.-Apr. 2002), https://www.researchgate.net/publication/11396187_The_use_of_fetal_bovine_serum_Ethical_or_scientific_problem (last visited Dec. 10, 2018).


ANIMAL LEGAL
DEFENSE FUND


AALI
Aquatic Animal
Law Initiative
Lewis & Clark Law School


COMPASSION
OVER KILLING


COMPASSION
in world farming
ciwf.com


FARMFORWARD


MERCY FOR
ANIMALS


the humane league™

Appendix A

ANIMAL LEGAL DEFENSE FUND EST 1979

525 East Cotati Avenue
Cotati, California 94931

T 707.795.2533
F 707.795.7280

info@aldf.org
aldf.org

September 25, 2018

Juanita Yates
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Submitted via electronic mail

Re: ALDF Comments Regarding Foods Produced Using Animal Cell Culture Technology; Docket No. FDA-2018-N2155

Dear Ms. Yates,

On behalf of the Animal Legal Defense Fund (ALDF) and the undersigned organizations, we write to provide comments in response to the Food and Drug Administration's (FDA) July 12, 2018, Public Meeting regarding Foods Produced Using Animal Cell Culture Technology.[1] We believe that this emerging technology has the potential to transform animal agriculture in profound and desperately needed ways. The detrimental impacts associated with the conventional production of meat, poultry, fish, and other animal-derived foods are well documented.[2] Producing these products through animal cell culture technology could massively reduce the animal suffering, environmental degradation, and public health risks associated with conventional animal agriculture. But fully achieving these benefits will require fair and thoughtful regulation by FDA and the U.S. Department of Agriculture that encourages innovation, ensures consumer confidence, and presents an efficient pathway to market.

[1] *See* Notice of Public Meeting; Request for Comments, 83 Fed. Reg. 28,238 (June 18, 2018).

[2] *E.g.*, American Society for the Prevention of Cruelty to Animals, *Factory Farming*, https://www.aspca.org/animal-cruelty/farm-animal-welfare; Gidon Eshel et al., *Land, Irrigation Water, Greenhouse Gas, and Reactive Nitrogen Burdens of Meat, Eggs, and Dairy Production in the United States*, 111(33) PNAS 11,996 (Aug. 2014); Gowri Koneswaran & Danielle Nierenberg, *Global Farm Animal Production and Global Warming: Impacting and Mitigating Climate Change*, 116(5) ENV. HEALTH PERSPECTIVE 578 (May 2008); Mary D. Barton, *Impact of Antibiotic Use in the Swine Industry*, 19 CURRENT OPINION MICROBIOLOGY 9 (June 2014).

ALDF commends FDA for its leadership in this area by taking proactive steps to identify a regulatory pathway that ensures food safety and consumer confidence in these new products.[3] FDA should build off its considerable experience with other cell culture technology applications, where consumer and food safety has already been well established, to establish the safety of these foods. An affirmative and transparent safety determination from FDA is an important step towards widespread market adoption of these transformative products.

Before turning to FDA's specific questions, ALDF notes that labeling and terminology are a central concern for these products—one that has received considerable attention recently.[4] Accurate labeling that does not unnecessarily thwart market adoption is crucial, and ALDF intends to address this topic in detail in subsequent comments in response to the FDA/USDA Joint Public Meeting scheduled for October of this year. These comments use the catch-all term "clean meat" for ease of reference, but ALDF recognizes the ongoing conversation about the appropriate statements of identity and labeling terminology that will accurately describe these products to consumers.[5]

I. Comments Addressing FDA's Specific Questions

Regarding FDA's specific questions focused on the production processes and food safety considerations associated with using animal cell cultures to produce food for human consumption, ALDF urges FDA to build off its considerable experience in regulating other cell culture applications where product safety has already been established.[6] FDA should identify and make available the least burdensome regulatory pathway that ensures product safety.

a. FDA Should Determine Safety in the Least Burdensome Way Possible, and No Foreseeable Scenario Would Require Animal Testing to Determine Safety

Depending on the final structure and composition of clean meat and similar products, FDA should apply the least burdensome regulatory pathway that ensures food safety and consumer confidence. Equally important to the actual pathway FDA determines is appropriate, FDA needs to clearly communicate its decision-making to producers and the public to establish regulatory certainty and consumer confidence as these products reach marketability.

---

[3] ALDF recognizes that FDA and USDA have also scheduled a Joint Public Meeting on this issue for October of this year. 83 Fed. Reg. 46,476 (Sept. 13, 2018). ALDF submits these comments to FDA now, but intends to supplement its comments in response to the Joint Public Meeting.

[4] *See*, *e.g.*, U.S. Cattlemen's Association, Petition for the Imposition of Beef and Meet Labeling Requirements: To Exclude Product Not Derived Directly from Animals Raised and Slaughtered from the Definition of "Beef" and "Meat," available at https://www.uscattlemen.org/Templates/pdfs_USCA/2018-PDFs/2-9-18USCA-AMS-Petition-re-definition-of-beef-and-meat.pdf ; David Meyer, *Tofurkey and the ACLU Are Teaming Up to Defeat Missouri's 'Fake Meat' Bill*, FORTUNE (Aug. 28, 2018), available at http://fortune.com/2018/08/28/tofurky-aclu-missouri-fake-meat-bill/.

[5] ALDF also notes the inadequacy of the term "clean meat" for FDA's purposes, as animal cell culture technology promises to enable the production of many more foods than are encompassed by the term "meat." These include cell-based alternatives to eggs, dairy milk, and foods derived from aquatic species, to name a few.

[6] These include, among others, spirulina extract, 21 C.F.R. 73.530; mycoprotein, GRN No. 91; and a variety of probiotics. *See*, Transcript of July 12 FDA Meeting at 23 ("For example, FDA has evaluated a variety of foods produced by cell culture, including microbial products such as probiotics, algal products such as spirulina and fungal products or the mycoprotein products as well." (statement by Dr. Susan T. Mayne, Director of the Center for Food Safety and Applied Nutrition)); 83 Fed. Reg. at 28,239 ("Currently, FDA evaluates microbial, algal, and fungal cells generated by large-scale culture and used as direct food ingredients . . . .").

If these final products are structurally, functionally, and chemically indistinguishable from their conventional counterparts, outwardly they would be the same as their counterpart products that were in wide use prior to January 1, 1958, and for which safe consumption has been widely accepted through "experience based on common use in food."[7] Thus, the question would be how FDA should address the "manufacturing process change" of producing meat and animal products through animal cell culture technology rather than through the conventional raising and slaughtering of live animals.[8]

While it is unclear if these final products, or the ingredients and processes involved, will constitute "food additives" under the Federal Food, Drug, & Cosmetics Act ("FDCA"),[9] a "generally recognized as safe," or GRAS, determination may be an appropriate avenue to ensure the safety of these products. As FDA stated, "The manufacturing process of a food substance is considered for the purposes of safety assessment *only insofar as it may affect the properties and safety of the finished product*."[10] Since it may be that these final products are structurally, functionally, and chemically indistinguishable from their conventional counterparts, it is unclear exactly what parts of the clean meat manufacturing process would be subject to a safety assessment. Yet, given these products' anticipated similarity to traditional foods with long histories of common use, and that they are being produced using manufacturing processes similar to other cellular agriculture foods and food additives that are GRAS, the GRAS determination could and probably should play a role in affirmatively establishing these products' safety.

With respect to any new safety authorizations that FDA may require, ALDF highlights and commends FDA's continued commitment to developing and implementing alternatives to animal testing.[11] FDA's involvement and experience with initiatives such as the Interagency Coordinating Committee on the Validation of Alternative Methods should inform this process and ensure that any and all alternatives to animal testing are made available to producers or regulators when ensuring the safety of these products. Any required safety authorization should not be determined through unreliable animal testing.

Putting aside the egregious harm to the animals used in such studies, the reliability of tests conducted on animals as models for humans has increasingly come into question. As one 2015 survey found, "animal experimentation is poorly predictive of human outcomes, [] is unreliable across a wide category of disease areas, and [] existing literature demonstrates the unreliability of

---

[7] 21 U.S.C. § 321(s); 21 C.F.R. § 170.30(d).

[8] *See* 21 C.F.R. § 170.30(d); FDA, Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives (June 2014), available at https://www.fda.gov/RegulatoryInformation/Guidances/ucm300661 htm (hereinafter "FDA Process Change Guidance").

[9] 21 U.S.C. §§ 301 *et seq.*

[10] FDA Process Change Guidance at 13 (emphasis added).

[11] "[W]e are working to reaffirm and strengthen our commitment to replacing, reducing, and/or refining animal studies, often referred to as the '3Rs.'" FDA, Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's Strengthened Commitment to Humane and Judicious Animal Research and the Termination of a Nicotine Study (Jan. 26, 2018), available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm594009.htm.

animal experimentation, thereby undermining scientific arguments in its favor."[12] In short, duplicative and imperfect animal tests should not be required to tell us what we already know: that meat and other animal-derived products can be safely consumed. And if safety tests are required, *in silico* models and "read-across" toxicology assessments should be utilized to the maximum extent possible.[13]

Given the above, FDA should not insist or rely on unreliable animal testing before it determines product safety or that the agency has "no questions" as to a submitter's GRAS notification. FDA's recently renewed and strengthened commitment to the "3Rs" (replacement, reduction, refinement) counsels in favor of considering and accepting appropriate alternative testing methodologies.[14]

b. The Use of Serum as A Growth Medium Presents Contamination and Consumer Transparency Challenges

Some animal cell culturing techniques require the input of serum derived from animal blood as part of the growth medium, the most common of which is fetal bovine serum (FBS).[15] The use of FBS in a product that reaches marketability raises serious question about potential contamination and consumer transparency. While several producers have stated publicly that they do not intend to use FBS or other animal-based growth medium to produce their products,[16] it remains unclear whether FDA will be tasked with assessing the in-market safety of products produced using FBS.

Serum-based media are known to pose functionality and contamination problems, because they are by-products of the cattle slaughter industry and thus are subject to source variability and all the contamination potential inherent in the slaughter of live animals.[17] Furthermore, because using

---

[12] Aysha Akhtar, *The Flaws and Human Harms of Animal Experimentation*, 24(4) CAMBRIDGE Q. HEALTHCARE ETHICS 407, 408 (Oct. 2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594046/pdf/S0963180115000079a.pdf.

[13] *See, e.g.*, Thomas Hartung, *Rebooting the Generally Recognized as Safe (GRAS) Approach for Food Additive Safety in the US*, 35(1) ALTEX (Dec. 18, 2017) at 9, available at https://www.altex.org/index.php/altex/article/download/95/140/; European Food Safety Authority, *New Tools to Potentially Reduce Need for Animal Testing*, https://www.efsa.europa.eu/en/press/news/170710; Hannu Raunio, In Silico *Toxicology—Non-Testing Methods*, 2(33) FRONTIERS PHARMACOLOGY (June 2011), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3129017/; Thomas Leuchtenfeld et al., *Machine Learning of Toxicological Big Data Enables Read-Across Structure Activity Relationships (RASAR) Outperform Animal Test Reproducibility*, 165(1) TOXICOLOGICAL SCI. 198 (Sept. 2018), available at https://academic.oup.com/toxsci/article/165/1/198/5043469; Bruce Friedrich, *Animal Testing & New Proteins: Time for FDA to Move Into the 21st Century*, GOOD FOOD INST. (Aug. 29, 2017), available at https://www.gfi.org/animal-testing-new-proteins-time-for-fda.

[14] *See* FDA, Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's Strengthened Commitment to Humane and Judicious Animal Research and the Termination of a Nicotine Study (Jan. 26, 2018), available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm594009 htm.

[15] Carlos E. Jochems et al, *The Use of Fetal Bovine Serum: Ethical or Scientific Problem?*, 30(2) ALTERN. LAB ANIM. 219 (Mar.-Apr. 2002), available at https://www.researchgate net/publication/11396187_The_use_of_fetal_bovine_serum_Ethical_or_scientific_problem.

[16] *See* Bruce Friedrich, *FBS & Clean Meat: The Future of Meat Is Slaughter-Free*, GOOD FOOD INST. (Aug. 4, 2017), available at https://www.gfi.org/the-future-of-meat-is-slaughter-free.

[17] *See* Megha S. Even et al., *Serum-free Hybridoma Culture: Ethical, Scientific and Safety Considerations*, 24(3) TRENDS IN BIOTECH. 105 (Mar. 2006), available at http://www.humaneresearch.org.au/campaigns/TRENDS_in_Biotech06.pdf; Jochems et al, *supra* note 15.

serum-based growth media in this context would require vast quantities of serum, compared with existing animal cell culture applications, previously identified functionality and contamination problems could be far greater if used in the commercial-scale production of clean meats and similar products.

Serum-free growth media that are chemically defined offer many benefits, and therefore FDA's safety evaluation should not impose unnecessary hurdles to the adoption of existing or newly developed serum-free media. There is a growing catalog of serum-free media for a variety of applications,[18] and producers' commitments to avoid FBS should be encouraged and enabled by FDA to the maximum extent possible.

Additionally, if FBS or another growth serum *does* play a role in the commercial production of these products, that should be made clear to consumers, who might otherwise believe that clean meat products are produced without dependence on animal slaughter.[19] FBS is harvested from the developed fetuses of cows found to be pregnant at slaughter via cardiac puncture, without any form of anesthesia or desensitization.[20] As such, products produced using FBS or other growth serum cannot be considered slaughter- or cruelty-free and should not be labeled to suggest otherwise (*e.g.*, vegan, humane, etc.). More and more consumers are demanding products that do not contribute to the animal suffering, environmental degradation, and public health risks associated with conventional animal agriculture,[21] and foods produced from animal cell cultures are positioned as an alternative that meets that demand. If serum-based media such as FBS are used in the commercial production of any of these foods, therefore, those products should be clearly distinguishable from ones that use serum-free media.

c. The Food Safety and Hazard Assessment for Clean Meats Is Dramatically Different Than That for Conventional Animal-Derived Products

The hazards associated with producing foods with animal cell cultures are vastly different than those associated with the conventional raising and slaughtering of animals. The basic reason for this is clear: clean meat production does not involve the myriad opportunities for contamination of the final product that are present in the raising and slaughtering of live animals. USDA's years of experience overseeing slaughter facilities provides all the evidence necessary of these contamination challenges.[22] Animals arrive at slaughter facilities filthy and often sick or injured from their time spent in unsanitary, crowded, stressful factory farms, and then from the intense stress of transport. Animals are then run through slaughter lines at break-neck speeds that hardly allow for individual

[18] *See* SEFREC Database, http://www.sefrec.com/.

[19] Bruce Friedrich, *FBS & Clean Meat: The Future of Meat is Slaughter-Free*, GOOD FOOD INSTITUTE (Aug. 4, 2017) https://www.gfi.org/the-future-of-meat-is-slaughter-free (describing the gradual phasing out of FBS).

[20] Jochems et al, *supra* note 15.

[21] *See, e.g.*, Animal Welfare Institute, *Consumer Perceptions of Farm Animal Welfare* (last updated Aug. 2018), available at https://awionline.org/sites/default/files/uploads/documents/fa-consumer_perceptionsoffarmwelfare_-112511.pdf (compilation of consumer research); Alice Hancock, *Younger Consumers Drive Shift to Ethical Products*, FINANCIAL TIMES (Dec. 22, 2017) https://www ft.com/content/8b08bf4c-e5a0-11e7-8b99-0191e45377ec.

[22] *See, e.g.*, USDA, FSIS Directive 6420.2 Rev.1, *Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations* (Apr. 27, 2017); Ted Genoways, *The Chain* (HarperCollins 2014).

inspection of animals and carcasses as they are processed.[23] The parts of these animals destined to become meat products are inevitably exposed to feces, entrails, blood, pus-filled abscesses, and a host of other potential sources of contamination.[24] These conditions explain one reason why USDA relies on consumers to ensure food safety through post-market safe handling and cooking.[25]

In contrast, the potential contamination risks involved in the production of clean meat and similar products are nothing like those described above. Instead, the necessary food safety control measures here are analogous to those already in use by other cellular agriculture applications, such as chymosin production for cheese-making.[26] FDA has already approved as GRAS other foods produced using cell culture technology, such as mycoprotein products that were issued a "no questions" letter by the FDA over 15 years ago.[27] Since the processes used to produce food from animal cell cultures are similar to these existing food production processes, with the primary difference being the type of cells being cultured, FDA should consider whether the control points and hazard assessments applied to those existing applications could, with minor adjustments, be applied here as well.[28]

II. Efficient Commercialization and Widespread Adoption of Clean Meat and Similar Products Would Dramatically Improve Animal Welfare, Environmental Sustainability, and Public Health and Wellness

The number of animals slaughtered for food in the United States is staggering. In 2017 alone, over 9 *billion* chickens,[29] 32.2 million cows, and 121.3 million hogs[30] were raised for slaughter. Untold numbers of salmon, tilapia, shrimp, squid, and other aquatic animals are harvested from the world's oceans, rivers, and lakes annually. Of those animals raised by humans, the vast majority

---

[23] *E.g.*, Animal Legal Defense Fund, *Stopping Cruel High-Speed Pig Slaughter* (Apr. 5, 2018), available at https://aldf.org/article/stopping-cruel-high-speed-pig-slaughter/.

[24] *See* Ted Genoways, *The Chain* (HarperCollins 2014); Andrea Rock, *How Safe Is Your Ground Beef?*, CONSUMER REPORTS (last updated Dec. 21, 2015), available at https://www.consumerreports.org/cro/food/how-safe-is-your-ground-beef (finding that "[a]ll 458 pounds of beef [Consumer Reports] examined contained bacteria that signified fecal contamination").

[25] *See* USDA, *Basics for Handling Food Safely*, available at https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/basics-for-handling-food-safely/ct_index.

[26] Valentin Waschulin & Liz Specht, *Cellular Agriculture: An Extension of Common Production Methods for Food*, GOOD FOOD INST., available at https://www.gfi.org/images/uploads/2018/03/Cellular-Agriculture-for-Animal-Protein.pdf: FDA GRN No. 230.

[27] FDA Response Letter GRAS Notice No. GRN 000091, available at https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=91; FDA GRN No. 230. (chymosin).

[28] Transcript of July 12 FDA Meeting at 178-181 ("The parallels that the agency can draw between products produced with animal cell culture technology and products produced with well-established microbial fermentation – also known as microbial cell factories – are pretty clear. Including the use of well-established safety evaluation decision trees such as the one in use by the enzyme industry. Granted, it would need some adaptation of course to fit the need for animal cell culture evaluation." (statement of Dr. Vincent Sewalt, DuPont Industrial Biosciences)); Valentin Waschulin & Liz Specht, *Cellular Agriculture: An Extension of Common Production Methods for Food*, GOOD FOOD INST., available at https://www.gfi.org/images/uploads/2018/03/Cellular-Agriculture-for-Animal-Protein.pdf.

[29] USDA, Poultry Slaughter 2017 Summary (Feb. 2018) at 5, available at http://usda.mannlib.cornell.edu/usda/current/PoulSlauSu/PoulSlauSu-02-26-2018.pdf.

[30] USDA, Livestock Slaughter 2017 Summary (Apr. 2018) at 6, available at http://usda.mannlib.cornell.edu/usda/current/LiveSlauSu/LiveSlauSu-04-18-2018.pdf.

experience intensive confinement in unsanitary, industrial factory farms.[31] These practices are inhumane, environmentally unsustainable, and a risk to public health. Clean meat offers an alternative that removes animal suffering from the production process and has the potential to drastically reduce environmental impacts and the risk of public health problems such as antibiotic-resistant "superbugs."

The billions of animals raised on factory farms each year suffer egregious and innumerable harms inherent to factory farming husbandry and slaughter. Numerous undercover investigations have revealed animal cruelty on factory farms that is hard to imagine.[32] By removing live animals from the production process, clean meats offer an alternative that would radically reduce animal suffering in our food system.

The anticipated environmental benefits of clean meat are also substantial, particularly in light of the growing threat from global climate change and the challenges of sustainably feeding an ever-growing world population. Because clean meat products are not yet being produced commercially, estimates of their environmental impacts are necessarily based on assumptions and different figures have been proffered—but all agree that significant reductions can be expected compared with current practices. Scientists from the University of Oxford and the University of Amsterdam have estimate that the production of clean meat instead of conventionally raising and slaughtering animals could reduce greenhouse gas emissions by up to 96%, energy use by up to 45%, land use by up to 99%, and water use by up to 96%.[33] Another thorough survey of currently available literature found that clean beef would entail a 95% reduction in land use, 74-87% reduction in greenhouse gas emissions, and a 94% reduction in nutrient pollution compared with conventional beef production.[34] Compared to conventional chicken production, clean chicken is expected to reduce land use by 35-67% and nutrient pollution by 70%.[35] Widespread adoption of clean meat products would result in a far more sustainable food system.

Clean meat also offers potential public health benefits. Conventional meat is a significant contributor to the spread of foodborne illness, which impacts 48 million people in the United States each year.[36] In contrast to the unsanitary conditions inherent to mass, high-speed slaughter of live animals, clean meats can be produced in highly controlled, aseptic environments that are far more sanitary than any factory farm or abattoir. Factory farms also engage in the widespread practice of administering antibiotics to animals in order to increase their growth rates and prevent diseases

---

[31] *See, e.g.*, Humane Society of the U.S., *An HSUS Report: The Welfare of Intensively Confined Animals in Battery Cages, Gestation Crates, and Veal Crates*, available at http://www humanesociety.org/assets/pdfs/farm/hsus-the-welfare-of-intensively-confined-animals.pdf.

[32] *See, e.g.*, ALDF, *Undercover Investigation Documents Tysons' Cruel, Illegal Treatment of Chickens* (Sept. 14, 2015), available at https://aldf.org/article/undercover-investigation-documents-tysons-cruel-illegal-treatment-of-chickens/; ALDF, *Investigation Reveals Cruelty and Neglect at Hormel Foods' Pig Supplier* (May 25, 2016), available at https://aldf.org/article/investigation-reveals-cruelty-and-neglect-at-hormel-foods-pig-supplier/; Compassion Over Killing, *Compassion Over Killing Investigations*, available at http://cok net/inv/ (compilation of COK investigations); Mercy For Animals, *Undercover Investigations*, available at https://mercyforanimals.org/investigations (compilation of MFA investigations).

[33] Press Release, *Lab-grown Meat Would "Cut Emissions and Save Energy,"* U. OF OXFORD (Jun. 21, 2011) http://www.ox.ac.uk/news/2011-06-21-lab-grown-meat-would-cut-emissions-and-save-energy.

[34] Good Food Inst., *Growing Meat Sustainably: The Clean Meat Revolution* 2 (2018).

[35] *Id.*

[36] Centers for Disease Control and Prevention, *Burden of Foodborne Illness: Findings* (last updated July 15, 2016), available at https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html.

endemic to factory farm conditions.[37] This overuse of antibiotics in animal agriculture is already resulting in antibiotic-resistant bacteria on food, which the Centers for Disease Control estimates impacts 400,000 people in the United States each year,[38] and in the environment generally.[39] Again in contrast, producing clean meat does not require this kind of antibiotics use.

A growing number of consumers are deciding that they cannot support such cruelty and are in search of humane alternatives.[40] Clean meat is uniquely positioned to fill this void by offering consumers meat, poultry, fish, etc. without the need to raise and slaughter live animals. We urge FDA to adopt an efficient and fair regulatory pathway to bring these products to market so that consumers may choose meat products that align with their values.

III. Conclusion

ALDF and the undersigned organizations strongly encourage FDA to facilitate an efficient pathway to market for clean meats and similar products. Whether FDA determines that these products are ultimately no different than their conventional counterparts and do not require new safety authorizations, or if a GRAS determination or other authorization is required, FDA should affirmatively communicate any eventual safety analyses and determinations to the public to ensure transparency and consumer confidence. FDA should adhere to its commitments to animal testing alternatives for any safety authorization that is required. Finally, FDA should ensure accurate labeling that adequately informs consumers, but should not require labeling that would effectively disparage the products in the eyes of consumers.

ALDF appreciates the opportunity to engage with this important process and looks forward to providing FDA and USDA further comments in response to the upcoming Joint Public Meeting on this issue.

Sincerely,

Animal Legal Defense Fund
Aquatic Animal Law Initiative
Compassion Over Killing
Farm Forward
Mercy For Animals
The Humane League

---

[37] *E.g.*, Felipe C. Cabello, *Heavy Use of Prophylactic Antibiotics in Aquaculture: A Growing Problem for Human and Animal Health and for the Environment*, 8(7) Environmental Microbiology 1137 (May 24, 2006), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1462-2920.2006.01054.x.

[38] Centers for Disease Control and Prevention, *Antibiotic Resistance, Food and Food-Producing Animals* (last updated July 24, 2017). https://www.cdc.gov/features/antibiotic-resistance-food/index.html.

[39] C. Lee Ventola, *The Antibiotic Resistance Crisis*, 40(4) PHARMACY & THERAPEUTICS 277 (Apr. 2015), available at https://www ncbi.nlm.nih.gov/pmc/articles/PMC4378521/.

[40] *See, e.g.*, Animal Welfare Institute, *Consumer Perceptions of Farm Animal Welfare* (last updated Aug. 2018), available at https://awionline.org/sites/default/files/uploads/documents/fa-consumer_perceptionsoffarmwelfare_-112511.pdf (compilation of consumer research); Alice Hancock, *Younger Consumers Drive Shift to Ethical Products*, FINANCIAL TIMES (Dec. 22, 2017) https://www ft.com/content/8b08bf4c-e5a0-11e7-8b99-0191e45377ec.


ANIMAL LEGAL
DEFENSE FUND


MERCY FOR
ANIMALS


COMPASSION
OVER KILLING


FARMFORWARD


Law Int
Lewis & Clark


the humane league™