

December 2, 2021

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*Re: Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells  
(Docket No. FSIS-2020-0036)*

Dear Ms. Edelstein:

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to respond to the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service’s (FSIS’s) “...advance notice of proposed rulemaking (ANPR) to request comments pertaining to the labeling of meat and poultry products comprised of or containing cultured cells derived from animals...” published in the Federal Register on September 3, 2021. Representing over 112,000 registered dietitian nutritionists (RDNs),<sup>1</sup> nutrition dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to improving the nation’s health through food and nutrition. Our members work in a variety of clinical and community settings across the continuum of care, and work with industry and consumers to develop and effectively utilize product labels that encourage individuals to make healthy food choices.

**The Academy supports FSIS’s efforts to inform future regulatory requirements for the labeling of cultured meat and poultry products<sup>2</sup> intended to prevent misbranding, and offers comments below responsive to questions posted in the ANPR. We have long been committed to working with government, industry, consumer, and scientific organizations in the hope of creating a balanced regulatory structure in the interest of consumers that can engender consensus support among stakeholders.**

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<sup>1</sup> The Academy approved the optional use of the credential “registered dietitian nutritionist (RDN)” by “registered dietitians (RDs)” to more accurately convey who they are and what they do as the nation’s food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

<sup>2</sup> Similarly to FSIS’s use in the ANPR, these comments typically refer to meat and poultry products produced using animal cell culture technology as “cultured” meat and poultry products or as products comprised of or containing “cultured” animal cells. As with the ANPR, the Academy’s use of this term as a convenience is not intended to establish or suggest an endorsement of preferred nomenclature for labeling purposes.

## **A. ACADEMY'S LABELING PRINCIPLES**

The Academy adopted in 2014 the following principles for labeling initiatives to guide our comments and policy stances. Those principles specifically relevant to the Academy's comments on FSIS's ANPR are bolded below and referenced as appropriate throughout these comments.

- 1. Label claims should be clear and understandable to consumers; consumers' nutrition literacy is key to promoting understanding.**
- 2. The label must be truthful and not misleading.**
- 3. Content on the label should help consumers make informed decisions to build a healthy diet.**
- 4. Labels should help to provide understanding about the nutrient density and overall healthfulness of overall food rather than a focus on particular nutrients.**
- 5. Label content should have consistent type and format so products can be read and consumers can make product comparisons.**
- 6. Labeling should enhance consistency among the various government nutrition recommendations.**
7. All claims should include labeling of accurate quantitative information about the dietary substance, including percent of Daily Value in a single serving of the products, when known, or the daily dietary intake necessary to achieve the claimed effect.
- 8. Consumer research is imperative before making changes to the label.**
9. The label is only a source of information, and thus sustained support for educational programs and individual counseling by registered dietitian nutritionists is essential.

The Academy convened representatives of our various Dietetics Practice Groups<sup>3</sup> for a discussion about regulatory issues associated with the labeling of cultured meat and poultry products and provide input in the application of our labeling principles to the questions posed in the ANPR. Our comments incorporate and reflect the consensus views arrived at during that meeting for a subset of the ANPR's questions.

## **B. Regulatory Need and Agency Jurisdiction**

Mitigating the impact of global climate change requires holistic solutions that engage all sectors of the economy, and we applaud the remarkable ingenuity and noble intentions of the scientists and entrepreneurs advancing these novel technologies. Given projected

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<sup>3</sup> Dietetic Practice Groups. Academy of Nutrition and Dietetics website. Available at <https://www.eatrightpro.org/membership/academy-groups/dietetic-practice-groups>. Accessed December 1, 2021.

increases in global meat consumption and its anticipated concomitant environmental impact, the promise of sustainable animal agriculture is exceptionally appealing.

The Academy applauds the USDA and the Food and Drug Administration (FDA) for their “joint formal agreement to jointly oversee the production of human food products comprised of or containing cultured cells derived from cell lines of those species covered under the Acts.”<sup>4</sup> This interagency cooperation is essential and should enhance consistency among government regulations to provide industry and consumers with regulatory clarity and certainty. The Academy encourages the agencies to continue the collaborative process by which it has engaged stakeholders on these issues to date as it develops, approves, and enforces a regulatory structure for the labeling of cultured meat and poultry products.

We note some industry leaders have indicated their desire to obtain guidance “under the current regulatory framework”<sup>5</sup> and tend to agree that it will be sufficient to address these novel regulatory issues. Accordingly, our comments presume application of existing regulations within the existing regulatory framework.

### **C. Questions Posed in the ANPR**

*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?*

The Academy strongly supports differentiating the product name of a meat or poultry product comprised of or containing cultured animal cells from the product from slaughtered meat or poultry by informing consumers in some readily understandable manner that the product was made using animal cell culture technology. Our labeling principles are clear that product labels must be truthful and not misleading and should be clear and understandable to consumers.

We question whether cultured meat would be considered “meat” under the existing regulatory definition in 9 C.F.R. 301.2.<sup>6</sup> The scaffolding onto which cultured animal tissue

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<sup>4</sup> ANPR at 49493.

<sup>5</sup> GFI Policy Director Jessica Almy said in a statement.”  
<https://www.forbes.com/sites/janetforgrieve/2018/11/19/federal-agencies-hammer-out-a-plan-to-regulate-cell-based-meats/?sh=2f437ab058bd>

<sup>6</sup> 9 C.F.R. 301.2 (Meat.

(1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

(i) Meat does not include the muscle found in the lips, snout, or ears.

(ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG)).

is grown does not seem to be “skeletal” (despite a similar function) nor would any harvested tissue have been “found in the tongue, diaphragm, heart, or esophagus” since none of those organs would be grown or present with the tissue. But even if it were to be deemed “meat,” the process by which the tissue of cultured meat is grown differs so significantly from conventional animal agriculture that differentiation in nomenclature is essential.

Differentiation could potentially be accomplished in a variety of ways and the Academy is not committed to any particular method or manner of labeling. However, any criteria should be simple and transparent and prioritize informing consumers over marketing to them, enabling a consumer (even with low nutrition literacy) to readily understand that cultured meat is produced differently and to make an informed decision about which product to purchase in alignment with his or her own value system. It would not be sufficient to have the differentiation made anywhere except the primary display panel in an easily and quickly readable font size and color.

*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.”)*

Lacking common usage of a particular name for novel products derived from cultured cells, the nascent industry over the past several years has attempted to coalesce around a succession of terms, including “lab-grown meat,” “cultured meat,” “clean meat,” “cell-based meat,” and now “cultivated meat.” Although the Academy strongly supports requiring use of a clarifying term 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, the Academy declines to suggest or endorse specific terms. Instead, in conjunction with our responses to other questions posed in the ANPR, specifically Question 4, we offer herein various reasons why the following specific terms might be improper or inappropriate for such purpose: cell-based meat, cellular meat, clean meat, cultured meat, and slaughter-free meat.

We appreciate the marketing importance of establishing a common or usual name that ranks highly for consumer appeal and commend FSIS in seeking economic data and consumer research to inform its decision making. Both quantitative and qualitative consumer research will be invaluable in ascertaining how these products should be labeled. The regulatory criteria for terms should prioritize the promotion of honesty and fair dealing in the interest of consumers,<sup>7</sup> recognize issues of safety, nutritional inferiority and bioequivalence, and account for factors that could render a term false or misleading. The name or a clarifying statement immediately following the name (e.g., “This product contains animal tissue...”) should make clear how the meat or poultry analogue was produced and differentiate it from conventional animal agriculture.

In light of the possibility (noted in our response to Question 1, above) that cultured meat and poultry products may not fit within the existing definition of “meat” in 9 C.F.R. 301.2, we encourage broader discussion as to whether cultured meat and poultry should be

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<sup>7</sup> 21 C.F.R. § 130.5(b).

deemed an imitation of conventional meat, given it is intended as a substitute for and resembles it. It is unclear, however, whether cultured meat products are nutritionally inferior to conventional meat, but we note that nutrients within a food often operate synergistically to produce health benefits and that different production methods can affect the bioavailability of nutrients. A product that has simply been fortified to contain the same amount of vitamins and minerals as the product it is imitating may still be nutritionally inferior to it; it will be critical to assess the bioequivalence and nutritional quality of cultured meat and poultry products and whether the method of production impacts it.

*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”)?*

The Academy believes that the use of the word “cultured” to describe meat or poultry products comprised of or containing cultured animal cells may create confusion, could have a different meaning than it has for other types of foods, and thus may be misleading to consumers. For example, 21 CFR 101.4(b)(5) specifies that “Bacterial cultures may be declared by the word “cultured” followed by the name of the substrate, e.g., ‘made from cultured skim milk or cultured buttermilk.’” Notably, the term “cultured” in the food name “cultured milk” modifies the preexisting food; it does not create a new food. For “cultured meat,” however, meat is not being modified by bacterial cultures; the culturing creates the food in the first place. “Cell-cultured meat” would at least be a more accurate term because it is stem cells that are cultured in the process, but such term is disfavored given the absence of any bacterial changes or fermentation that characterizes use of the term “cultured” for other food types. 21 CFR 864.2280(a)<sup>8</sup> suggests that another possibility could be the term “cultured animal cell meat” or the phrase “meat cultivated from cultured animal cells.”

*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?*

Consumers are entitled to material information about how their food is produced. Thus, the Academy believes that all products produced in-whole or in-part from cultured animal cells should provide consumers with information about the source material in a readily accessible and understandable manner on the primary display panel. If both slaughtered meat and cultured meat products are used in a product, the product should be labeled on the principal display panel to indicate that composition and the percentage of each type of meat or meat product in the product (e.g., “50% of meat derived from cultured animal cells”).

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<sup>8</sup> 21 CFR 864.2280(a) (Identification. Cultured animal and human cells are in vitro cultivated cell lines from the tissue of humans or other animals which are used in various diagnostic procedures, particularly diagnostic virology and cytogenetic studies.).

*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.*

A number of terms would be potentially false or misleading to consumers, including “cell-based meat,” “cellular meat,” “clean meat,” “cultured meat,” “slaughter-free meat,” “cruelty free meat,” and “sustainable meat.” First and foremost, we reiterate that marketing-friendly terms designed to advance relative or comparative merits are not appropriate unless they provide clarity as to the actual process used. For example, “clean meat” is an inherently relative term that provides nothing from which consumers could readily infer any objective information or differentiate it from other meat products. In addition, we note that many commentators have questioned whether there is sufficient data available to assess the environmental impact of cultured meat and poultry products to even ascertain a comparison to other meat production methods. The term “sustainable meat” asserts facts not (yet) in evidence, but more importantly fails to provide information about the actual process that would putatively make it the more sustainable option. “Cell-based meat” provides some accurate information about the process, but because *all* meat is cell-based, it is misleading and fails to differentiate it from conventional meat.

*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.*

The Academy identifies “lab-grown meat,” “laboratory-grown meat,” “synthetic meat,” and “artificial meat” as terms that would potentially have a negative impact on industry, to whom we defer regarding terms with a negative perception. We recognize industry’s interest in selecting an appropriate and marketable term and would not support establishing a name that diminishes consumer demand.

*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?*

The Academy anticipates that technology may develop such that cultured meat and poultry products will be produced that has the same characteristics as slaughtered meat and poultry products established by common usage, and to the extent that the organoleptic properties are the same, we would support the use of those names alongside the modifier used to denote the meat or poultry products were derived from cultured animal cells.

*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?*

There are many unknown properties of cultured meat and poultry, and we applaud industry's commitment to transparency as important to secure consumers' confidence and convey information material to their health and safety. For example, we seek clarification regarding the extent to which the cell culture nutrient medium, which provides the fuel for cell growth, other reagents or components of the meat analogue should be declared a food additive pursuant to 21 C.F.R. 170.3(e)(1)<sup>9</sup> and thus subject to extensive oversight before eligible for sale to consumers. Relatedly, it is unclear what the environmental and health impacts of the newly formulated nutrient medium materials are, whether they contain growth hormones or antibiotics, and if so, whether residue will be present in consumer food products. Many of our Dietetic Practice Groups emphasized the need for a better understanding of the long-term health effects of cultured meat and poultry products.

Moreover, because of understandable technological, cost, and other limitations, consumers have yet to have the opportunity to consume cultured meat that has the vascular structure and other characteristics of complex cuts of meats, such as steaks. Although we understand a 3-D-printed "steak" has been created, we believe it is premature to sufficiently assess organoleptic (e.g., appearance, odor, taste) characteristics and note the fact that the steak was printed confirms a substantial underlying difference between conventional and cultured meat products. Similarly, we lack the ability to assess the nutritional, biological, and chemical characteristics of products not yet ready for consumer sale. There is also little available information about the bioavailability of nutrients in, or the nutrient density of, cultured meat and poultry products

*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?*

As noted in Question 1, above, the Academy questions whether cultured meat would be considered "meat" under the existing regulatory definition in 9 C.F.R. 301.2.

*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?*

Consumers are entitled to material information about how their food is produced. Thus, the Academy believes that all products produced in-whole or in-part from cultured animal cells should provide consumers with information about the source material in a readily accessible and understandable manner on the primary display panel.

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<sup>9</sup> 21 C.F.R. 170.3(e)(1) ("Food additives includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food.").

*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?*

Consumers are entitled to material information about how their food is produced. Thus, the Academy believes that all products produced in-whole or in-part from cultured animal cells should provide consumers with information about the source material in a readily accessible and understandable manner on the primary display panel. Further processing should not obviate the need to provide consumers with this information.

*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?*

The Academy anticipates that industry will label some FSIS-regulated products comprised of or containing cultured animal cells with available nutrient content claims. Owing to the fact that cultured meat products often do not contain the same saturated fats associated with conventional meat, we are likely to see fat content claims such as “lower fat,” “reduced fat,” “lite” or “light” pursuant to 21 C.F.R. 101.62(b), fatty acid content claims pursuant to 21 C.F.R. 101.62(c), cholesterol content claims pursuant to 21 C.F.R. 101.62(d), and “lean” or “extra lean” claims pursuant to 21 C.F.R. 101.62(e). FSIS should ensure through product testing and consumer research that consumers are not misled and should continue its process of open engagement with stakeholders to consider the potential falsity of any such claims.

#### **D. Conclusion**

The Academy appreciates the opportunity to comment on the ANPR for the labeling of meat and poultry products comprised of or containing cultured cells derived from animals. Please contact either Jeanne Blankenship at 312-899-1730 or by email at [jblankenship@eatright.org](mailto:jblankenship@eatright.org) or Pepin Tuma at 202-775-8277 x6001 or by email at [ptuma@eatright.org](mailto:ptuma@eatright.org) with any questions or requests for additional information.

Sincerely,



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