

December 2, 2021

By Electronic Submission

Docket No. FSIS-2020-0036
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue, N.W.
Washington, DC 20250-3700

Re: Comments on Advanced Notice of Proposed Rulemaking for the Labeling of Meat and Poultry Products Containing Cultured Meat and Poultry Cells

The Center for Science in the Public Interest¹ and Consumer Federation of America² appreciate the opportunity to submit comments to the Food Safety and Inspection Service (FSIS) on its advanced notice of proposed rulemaking (ANPR) involving questions about how meat and poultry products comprised of, or containing, cultured meat and poultry cells should be labeled.

USDA (along with FDA for the cell-cultured animal products it regulates) has an opportunity to establish naming conventions for a new and growing category of products with which consumers are not yet familiar. Choosing the terms that should be included in the name or standard of identity of products from animal cell culture technology is crucial to the successful adoption of these novel food products and the appropriate informing of consumers. USDA's leadership in this arena can influence marketplace success, consumer confidence, and even naming conventions for cell-cultured meat and poultry in other countries around the world.

¹ The Center for Science in the Public Interest (CSPI) is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by 400,000 member-subscribers to *Nutrition Action* and by foundation grants. CSPI receives no funding from industry and no grants from the federal government.

² The Consumer Federation of America (CFA) is an association of non-profit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. Today, more than 250 of these groups participate in the federation and govern it through their representatives on the organization's Board of Directors.

We agree with USDA that all labels for cell-cultured products under FSIS jurisdiction should be subject to premarket review under the same process as other special statements or claims. USDA needs to ensure that whatever term it decides upon for these products is applied uniformly and presented with any necessary explanatory or qualifying text. The individual review of each label is important because, as USDA states, there is not widespread industry understanding of the labeling requirements and “consumers have not yet had experience reading these types of labels.”

While we do not propose a particular phrase for identifying cell-cultured³ foods for consumers, we believe USDA and FDA jointly should select a phrase that is accurate, neutral, and informative to consumers. It would needlessly confuse consumers if meat and poultry products used one term (*e.g.*, cell-cultured) while seafood products used a different term (*e.g.*, cell-based). Different terms could lead consumers to believe that products were produced using different technologies or methods when they were not. With such a new technology, and one that is not well known to consumers, it would facilitate consumer understanding if products that are similarly produced also are labeled using the same words or phrases, regardless of the agency that regulates them. FDA and USDA should agree on the specific terms that will be used to identify these products to consumers and ensure that the foods derived from cell-cultured animal cells use those terms to promote consumer understanding and prevent consumer confusion. The standards for label claims that cell-cultured product producers may wish to use to market their products, such as specifying input composition or sourcing (*e.g.*, produced with or without media derived from fetal bovine serum), should be harmonized between the agencies as well.

USDA and FDA have agreed to share regulatory oversight of cell-cultured meat and poultry products, with FDA overseeing the safety of the initial cell lines, the inputs into the production process, and the fermentation process up until harvest, and USDA overseeing processing and labeling. USDA must maintain communication with FDA regarding the latter agency’s conclusions about safety and the equivalence of these products to their traditional counterparts so that USDA can ensure that labels disclose any relevant safety concerns or nutritional differences. For example, USDA should require that labels alert consumers to characteristics of cell-cultured products that FDA identifies such as: (1) an allergenic compound was used in the production process, (2) the product needs different handling instructions than its traditional counterpart to remain safe once it

³ The ANPR refers to “cultured animal cells” for the food products which they are considering how to label. For the remainder of this comment, we refer to these food products as “cell cultured.” While we believe USDA should consider “cell-cultured” as one possible term to label these foods, we are not endorsing that terminology as the best or only phrase that would satisfy the criteria we set forth in the comment and meet USDA’s regulatory obligations. Other terms such as “cell-based” may also be acceptable.

is purchased by the consumer; or (3) the product is nutritionally different from its traditional counterpart in a way that has a potential impact on health.

The cell-cultured meat and poultry industries and products are in their infancy and could substantially change in the coming years. USDA and FDA should acknowledge that the labelling rules that are developed at this time could become outdated. In addition, USDA and FDA should outline a process for continuously gathering more data from all stakeholders on the cell-cultured products and technology and a process for timely amendments to the labeling rules as needed.

As requested by USDA in the ANPR, we are providing the following answers to the questions posed by FSIS.

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?

Cell-cultured meat and poultry products should have labels with a standardized, descriptive term that conveys to consumers how they are different from meat and poultry products produced using traditional methods. The term should be accurate, non-misleading, informative, accessible, and not result in consumer confusion.

We believe that the best way to label cell-cultured meat and poultry products is to use the common name of the comparable traditional product but qualify that name with words that signal to the consumer that the product is one made with cell-culture technology. For example, a product would be labeled “Ground Beef” with the words “Cell-Cultured” in prominent print in close proximity. It is critical that the accompanying qualifiers distinguish for the consumer the differences in production processes with clarity and transparency.

The chosen accompanying qualifier language should be required for all cell-cultured meat and poultry products, as the method of production does not at present vary significantly enough between animal species to justify establishing different qualifiers for different species or products. Use of the same term will enhance consumer recognition and understanding of the new products as consumers learn to identify a specific, standardized term with the new technology. If non-standardized qualifying terms are used for different species, consumers could be misled into thinking that cell-cultured beef, pork, poultry, etc. are not produced using the same general production methods when in fact they are.

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

To inform USDA about which possible terms would meet its regulatory obligations, USDA should conduct consumer research, such as surveys and/or focus groups. In addition, USDA should consult peer-reviewed studies (such as the Hallman and Hallman studies identified below) that have examined possible nomenclature for cell-cultured products. Objective data and analysis on consumer perceptions of different terms will help USDA make an informed and reasoned decision on the best label statement.

To help with the design of its own studies, we encourage USDA to review the work of William K. Hallman and William K. Hallman II.⁴ While those studies focused on the terminology for seafood products, they were conducted with an eye towards addressing federal regulatory considerations, and the results seem equally applicable to meat and poultry. In particular, the studies analyze potential labeling terms on the basis of five regulatory and market criteria, i.e. whether a labeling term: (1) allows the consumer to differentiate the product from conventionally produced product; (2) identifies potential allergenicity; (3) is seen by the consumer as an appropriate term to identify the product; (4) is not disparaging to the cell-cultured products nor the traditional products; and (5) does not elicit responses that the products are not nutritious, healthy, or safe. We recommend that USDA use similar criteria in its own research when deciding what label information to provide consumers.

Based on the results of the two Hallman and Hallman studies, there is evidence to support both “cell-cultured” and “cell-based” as terms that would inform consumers of material facts and not be misleading, as well as portray the product in a neutral fashion. (“Cell-cultivated” was not tested.) USDA, in conjunction with FDA, should closely consider these options, other peer-reviewed studies, and its own studies before making a final decision on its final label phrase.

⁴ See William K. Hallman and William K. Hallman II. “An empirical assessment of common or usual names to label cell-based seafood products,” *Journal of Food Science*, vol. 85:8 (2020) doi: 10.1111/1750-3841.15351; William K. Hallman and William K. Hallman II, “A Comparison of Cell-Based and Cell-Cultured as Appropriate Common or Usual Names to Label Products Made from the Cells of Fish.” 2021, *Journal of Food Science*, <https://doi.org/10.1101/2021.02.26.433119>.

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?

Products in the first generation of cell-cultured meat or poultry sold to consumers might contain a mixture of cell-cultured meat or poultry and traditionally produced meat or poultry. The first cell-cultured meat products will be more costly to produce than their conventional counterparts, and many consumers will pay a premium for cell-cultured products because they have attributes or benefits that they wish to support, such as increased sustainability, reduced carbon footprint, or reduction in animal suffering (all claims which currently have been identified by different developers, but not independently verified). Producers may have an incentive to misrepresent products with a mix of slaughtered meat and cultured animal cells.

If a consumer purchased a cell-cultured hamburger because they believed the method of production was more sustainable, only to learn that the product contained just a small amount of cell-cultured protein and a large amount of conventional animal protein, they could very well be misled. To prevent cell-cultured products from misleading consumers, USDA should require such “mixed” product labels to include disclaimers on labels such as “Product contains both meat from both cell-cultured animal cells and slaughtered livestock.” USDA should further require product labels to clearly identify the percentage of meat or poultry protein attributable to cell-culture technology and the amount that comes from other methods of production. When a product is fully cell-cultured, it would be best if it included 100% on the product label.

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.

Many proposed terms from different stakeholders for cell-cultured meat and poultry are misleading and some may not be accurate (*e.g.*, if they do not convey to the consumer how the product was produced and how it is different from the traditional product). These terms should not be allowed by USDA.

Some of the terms suggested by opponents of the technology seem intended to stigmatize these products. It may not be clear to consumers what those terms, such as “synthetic” and “artificial,” mean for this set of products. Such terms, which are already in use on foods (particularly “artificial”), likely fail to adequately convey the distinctions related to production methods that characterize these foods.

Similarly, USDA should eliminate some terminology which has been proposed by product developers to make implicit claims of superiority. Those terms could be perceived by consumers as creating the perception of product benefits that may not be rooted in facts. For example, labeling cell-cultured meat and poultry “clean” implies that the product cannot contain pathogens or other contaminants, even though contamination is possible. Furthermore, “clean meat” does not tell the consumer what technology was used to create the cell-based product. It also implies that conventional meat products are inherently “dirty.” Similarly, terms such as “humane” or “cruelty-free” fail to inform the consumer about how cell-based production differs from traditional meat and poultry.

Two other proposed terms are “cultivated” and “cultured.” Without further qualification of those terms, we note that they are not appropriate for labeling because they do not appropriately convey for consumers how the products were produced.

“Cultivated” terminology has been embraced by proponents of the cell-cultured protein products and stems from the use of meat *cultivators* (bioreactors) in the production process of cell-based foods.⁵ While those versed in the science and business of cellular agriculture may recognize that a “cultivated” product refers to meat or poultry produced using cultivators, average consumers may not understand the reference and may view all meat and poultry as the product of cultivated animals. Many consumers may not understand how a cultivated meat product is distinct from a traditional meat product, nor would it be conveyed by the term.

In addition, the term “cultured,” when used alone, is confusing because it does not include *what* was cultured to produce the meat and could not reasonably be inferred to refer to cell culture technology (especially by consumers who are not even aware that this new technology exists). “Cultured” also has a recognized meaning as fermented, *e.g.*, cultured dairy products like cheese, yogurt, and kefir, which may confuse consumers into thinking they are purchasing a fermented product. “Cultured meat,” while factually correct (since the meat is produced from cells grown in a cell culture medium), does not accurately communicate to consumers how the product is different from traditional 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.

Please see our answer to question #4 above. In addition, several additional terms for cell-cultured meat could have a negative impact on industry or consumers. For example, “laboratory-grown” could lead consumers to believe that the meat comes from

⁵ Friedrich, Bruce. “Cultivated meat: Why GFI is embracing new language,” Good Food Institute, Sept. 13, 2019. At <https://gfi.org/blog/cultivatedmeat/>

animals grown in a lab. “Vat grown” is an unappetizing and possibly inaccurate term. “In vitro” would be largely unfamiliar and therefore uninformative to most people. Moreover, each of these terms are less precise than “cell-cultured,” “cell-based,” or “cell-cultivated.”

6. Should names for slaughtered meat and poultry products established by common usage (e.g., Pork Loin), statute, or regulation be included in the names or standards of identity of such products derived from cultured animal cells? a. If so, is additional qualifying language necessary? What qualifying terms or phrases would be appropriate? b. Do these names, with or without qualifying language, clearly distinguish foods comprised of or containing cultured animal cells from slaughtered products?

It is premature to answer this question because, while cell-cultured products may be able to mirror the primary cellular composition of certain slaughtered meat and poultry products, their ability to reproduce highly structured muscle composition has yet to be demonstrated. There could be substantial differences in organized fibers, blood vessels, nerves, connective tissue, and fat cells, in addition to distinguishing properties provided by cell growth media or other ubiquitous chemical inputs. These differences may lead to substantial differences in cell-cultured products’ nutritional value, ability to tolerate cooking techniques, and the final taste and texture. Therefore, to prevent consumers from being misled, FSIS might need to issue a SOI, guidance or additional labeling requirements (e.g., “texture or taste may differ from a slaughtered pig loin.”) before any claim implying identity between particular cuts of slaughtered meat and cell-cultured meat could be used.

To the consumer, meat and poultry product names which often refer to specific structured muscle products being associated with cell-cultured products may be misleading if those products have differences from the comparable slaughtered product. FSIS has a responsibility to ensure that consumers understand that the product is different from a loin, steak, or other cut of meat from a slaughtered animal. meat (by being labeled “cell cultured”) and that any common usage name (such as loin or steak) results in a product that meets consumers expectations and understanding of that term. Such common usage terms have meaning and value to consumers, and confusion will ensue if producers can affix those terms to non-identical products.⁶

⁶ To prevent consumers from being misled, FSIS might need to establish different standards of identify or issue guidance for how common terms to describe certain meat and poultry products may be used on cell-cultured products. For example, FSIS could require a disclosure similar to that required for “bacon-like products.” In that case, the agency allows a variety of “coined names” such as “Turkey Bacon,” but requires a “true descriptive name” such as “Cured Turkey Breast Meat—Chopped and Formed” that “must appear contiguous to (Kind) Bacon without intervening type or design, in letters at least one-half the size of the letters used in the (Kind) Bacon, and in the same style and color and on the same background.” Similarly, FSIS could allow a coined name such as “Cell-Cultured Sirloin Steak” with a true descriptive name such as “cells from beef sirloin grown and formed” following a similar set of requirements for location, size, style, and color of the disclosure.

The details of FSIS's guidance, SOI, or label requirements may depend on which products are developed and the technologies and processes used to develop them. FSIS should follow the progress of the cell-cultured meat industry closely, understand the commercial products they are developing, and determine the best way to ensure those products are adequately labeled so they don't mislead consumers. When FSIS is deciding how to proceed, it should do so with sufficient stakeholder engagement to promote consumer confidence in these products.

7. Should terms that specify the form of meat or poultry products (such as "fillet", "patty", or "steak") be allowed to be included in or to accompany the name or standard of identity of foods comprised of or containing cultured animal cells? a. Under what circumstances should these terms be used? b. What information would these terms convey to consumers?

Please see our answer to question #6 above.

8. Should FSIS establish a regulatory standard of identity under its authorities in the FMIA and the PPIA (21 U.S.C. 607(c) and 457(b)) for foods comprised of or containing cultured animal cells? a. If so, what would be the standard and how might compliance with the standard be verified? b. If so, what would be the labeling terminology for products that do and do not meet a formal standard of identity? What would be the anticipated categories of use? For example, mechanically separated poultry that does not meet the standards of identity outlined in 9 CFR 381.173 may be diverted for production in broths and bases, as well as reaction flavors, i.e., flavors produced by the heating of the protein source in the presence of a reducing sugar. c. If so, what are the benefits and costs to industry if the standard of identity is established? Please provide quantitative and qualitative feedback in your response and explain the basis of any quantitative estimates. d. If so, what are the consumer benefits and costs to the standard of identity recommended?

We believe that cell-cultured products are covered under FMIA and PPIA. As discussed in our response to question #6, cell-cultured products could differ substantially from slaughtered animal products. As technology and knowledge of the industry increase over time, FSIS should review the products that are being developed and determine whether standards of identity are necessary to prevent misleading consumers beyond requiring that products be labelled using terms to inform consumers of potential differences between cell-cultured products and slaughtered animal products.

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?

As discussed in #6 above, there could be substantial organoleptic, biological, chemical, and nutritional differences between cell-cultured products and slaughtered meat and poultry products which would be relevant to consumers.

FSIS and the cell-cultured meat and poultry industry should conduct extensive outreach and engagement to ensure that consumers are aware of key differences between cell-cultured products and slaughtered meat and poultry products. As consumers are unable to discern nutritional qualities that may have an impact on their health, FSIS should be prepared to expeditiously analyze the nutritional makeup of at least the initial cell-cultured products as they are prepared to enter the market. The agency should develop a predetermined set of key nutritional characteristics that are present in comparable slaughtered meat and poultry products and convey to consumers any ways in which cell-cultured products substantially vary from these characteristics, potentially through labelling requirements.⁷ This will protect consumers from being misled about the nutritional quality of these products and could also help build consumer confidence in this fledgling FSIS-regulated industry.

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?

We believe that cell-cultured meat is currently included in the definitions identified because the cells from which the product is formed come from the muscle of cattle, sheep, swine, or goats. However, if USDA interprets those definitions to either not include cell-cultured meat or be unclear about whether they include cell-cultured meat, we support USDA amending the definitions to specifically include foods comprised of or containing cultured animal cells.

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

Similarly, cell-cultured poultry should be considered a “poultry product” or a “poultry food product.” If USDA does not already consider cell-cultured poultry to be included in those definitions, then we would support USDA amending those definitions to include foods comprised of or containing cultured animal cells.

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 sublisting, or elsewhere on the label?

No response at this time.

⁷ For further discussion of identifying key nutritional characteristics that are of public health significance, see CSPI’s 2019 comments to the FDA on the use of dairy names in the labeling of plant-based products: <https://cspinet.org/sites/default/files/attachment/CSPI%20Dairy%20Alternatives%20Comment.pdf> ; and CFA’s comments: <https://consumerfed.org/wp-content/uploads/2019/01/dairy-standards-of-identity-comments.pdf>

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?

If cell-cultured meat is an ingredient in a processed food product, the incorporation of cell-cultured meat should be identified on the product label. At a minimum, the product's ingredient list should be required to specify "cell-cultured beef" instead of "beef." In addition, if meat or poultry is included in the common product name, such as "beef lasagna," the product name on the label should have an asterisk and an explanation at the bottom of the principal display panel of the package that the beef is "cell-cultured."

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?

It is not yet clear what label claims will appear on cell-cultured meat and poultry. The claims will likely relate to benefits of the product, distinctions between different cell-cultured products, or between those products and traditional meat and poultry products. If products want to make benefit claims related to health, safety, nutrition, or sustainability, FSIS should develop new regulations or guidance on such claims to inform the industry and consumers about which claims will be allowed and the evidence or documentation needed to support those claims. USDA could look to how FDA regulates similar claims for conventionally produced food when setting forth its evidentiary requirements. USDA may want to address specifically potential claims made by products that their cell-cultured product is safer than either another cell-cultured product or a traditional meat or poultry product.

We appreciate the opportunity to provide this comment to USDA. We would welcome the opportunity to meet with the staff at USDA to discuss the issues addressed in this letter in more detail if that would be helpful.

Sincerely,

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