

United States Senate

WASHINGTON, DC 20510

COMMITTEES:
ARMED SERVICES
BANKING, HOUSING, AND
URBAN AFFAIRS
FOREIGN RELATIONS
INDIAN AFFAIRS
VETERANS' AFFAIRS

December 2, 2021

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

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

I write today regarding the Advance Notice of Proposed Rulemaking (ANPRM) published in the Federal Register by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) on September 3, 2021, entitled "Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells" (Docket No. FSIS-2020-0036). Thank you for the opportunity to provide comment on an issue of critical importance to both consumers and producers.

Simply put, lab grown food products are not equivalent to meat and poultry products born, raised and harvested in the traditional manner. Pursuant to applicable federal laws, the FSIS should promulgate clear, accurate and fair regulations governing the labeling of these cell cultured foods so they cannot be confused with traditional meat and poultry products. Because this new technology has yet to reach commercial scale or a broad level of public awareness, consumers are substantially unacquainted with these products and their nutritional properties. In fact, the impact on human health when consuming these products is unknown due to a lack of longitudinal data. This is especially true relative to carefully studied meat and poultry products enjoyed by consumers for hundreds of years. My constituents are concerned that imprecise labeling regulations could result in consumers being placed at a disadvantage when attempting to make informed decisions.

Lab grown products should be recognized in the marketplace based upon their standalone reputation, not the hard-fought reputation achieved by our nation's agricultural producers. This consideration, in part, has led a majority of states to either pass or introduce legislation to prohibit cell cultured food from receiving labels that conflate these products with meat.¹

The Federal Meat Inspection Act (21 U.S.C. § 607(c)) and the Poultry Products Inspection Act (21 U.S.C. § 457(b)) grant the USDA statutory authority to develop regulations governing the content of labels affixed to meat and poultry products. It is expected that rules will implement federal law as Congress intended. Under existing federal law, Congress did not intend for lab grown products to be labeled as meat or poultry.

Unfortunately, the federal government has failed to develop labeling regulations consistent with the expectations of consumers or the needs of producers. For example, under current labeling regulations, beef derived from cattle born and raised outside of the United States is inexplicably allowed to use the "Product of the U.S." label.² To the detriment of the

¹ <https://www.nyuelj.org/wp-content/uploads/2021/04/Pitkoff-State-Bans-on-Labeling-for-Alternative-Meat-Products-1.pdf>

² <https://www.agri-pulse.com/articles/16122-usda-to-conduct-top-to-bottom-review-of-product-of-the-usa-meat-labels>

nation's dairy producers, liquid products containing no milk are allowed to be labeled as milk.³ Plant-based products containing no eggs are allowed to be labeled "JUST Egg."⁴ Juice labeled "Simply Watermelon" contains cherry juice.⁵ Although some of these products are required to have labelling content that accurately informs consumers, this information often appears in smaller font on less prominent areas of the product container.

These are merely a few examples in which the USDA and the Food and Drug Administration have not met the commonsense expectations of the American consumer. Previously issued regulations of this type should be reversed as soon as possible, and future regulatory decisions should not be premised upon the same flawed basis or rationale.

On October 6, 2021, the USDA announced the award of a multi-year, multi-million dollar grant which will assist the cell cultured food industry at the direct expense of traditional agriculture.⁶ This announcement was met with dismay and confusion by many of my constituents. Regrettably, this grant funding suggests a degree of bias that the USDA should address prior to issuing labeling regulations that could unfairly benefit the lab grown food industry.

Specifically, the FSIS should consider these comments to the enumerated questions within the ANPRM:

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?

Yes. It is critical that the product name clearly and unequivocally notifies consumers that they are consuming a lab grown imitation of a meat or poultry product. The principle consideration should be accuracy. Prohibiting the use of the terms meat, poultry, beef, pork, etc., would be the most helpful course of action in allowing consumers to differentiate lab grown foods from bona fide meat and poultry. The FSIS should establish criteria by which these familiar and established terms are not expropriated by a product category with a low level of consumer awareness.

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.")

Terms such as "cell cultured", "cell cultivated", "lab grown" and "non-meat or poultry animal product," as well as descriptive adjectives such as "fake," "synthetic," "artificial" and "imitation" should be considered.

a. How do these terms inform consumers of the nature or source of the product?

These terms convey to consumers that although animal cells were involved in the production of these foods, these products are not the well-known meat and poultry products they are familiar with. These terms and combinations thereof must also acknowledge the presence of animal cells to allow consumers to forego these products for religious, ideological, allergenic and food sensitivity reasons.

b. What are the benefits or costs to industry and consumers associated with these terms?

Labeling regulations that allow for the appropriation of established terms such as meat and poultry could have a multi-billion dollar negative economic impact. This is an undisputed market share reality that is acknowledged worldwide. For example, countries such as Italy, France and Japan have vigorously fought global efforts to dilute the meaning of established product names such as Chianti, Champagne and Wagyu. States such as South Dakota rely heavily on animal agriculture, and the sector is a major contributor to the nation's economic vitality.⁷ Misleading or incomplete labeling practices represent a clear and present threat to animal agriculture and the millions of jobs supported by the industry.

³ <https://finance.yahoo.com/news/plant-based-milk-market-surpass-143000853.html>

⁴ <https://www.target.com/p/just-egg-plant-based-egg-12-fl-oz/-/A-82029391>

⁵ <https://www.kroger.com/p/simply-watermelon-fruit-juice-drink/0002500010211>

⁶ <https://www.usda.gov/media/press-releases/2021/10/06/usda-announces-more-146m-investment-sustainable-agricultural>

⁷ <https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy/>

Consumers would also suffer harm from the use of inaccurate food labels. Freedom of choice is a bedrock American value. This is particularly important with regard to nutritional decisions we make both for ourselves and our families. The improper use of terms with clear meaning in the public consciousness would inevitably lead to confusion.

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”)?

Yes. As previously stated, the FSIS should consider the use of the term “cell cultured” to alleviate the potential for confusion with other products, including other cultured products.

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?

For products that contain a combination of meat or poultry and lab grown food, the required label should inform consumers that the content of the product is of multiple origins. The FSIS should also consider a requirement that these combination products indicate what percentage by weight of each type of food is present.

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.

Various terms currently applied to traditional products derived from animals should be prohibited in order to avoid consumer confusion. These include:

- “Meat” or “poultry.” Lab grown cells do not presently nor have they ever been considered meat or poultry according to any reasonable definition of these terms in either statute, regulation or the public consciousness. Even many natural animal products, such as bone marrow, do not constitute meat. In addition, the statutory definition of a meat food product explicitly prohibits the use of this term for products that “historically have not been considered by consumers as products of the meat food industry” (21 U.S.C. § 601(j)).
- “Meat byproduct” or “poultry byproduct.” These terms are inherently associated with food products that are comprised of animal cells that are naturally produced. Utilizing these terms when referring to lab grown food products is confusing and misleading.
- “Farm raised,” “pasture raised,” “organic,” “grass fed” or “free range.” Cell cultured products should not be allowed to claim the use of husbandry techniques that were not employed for the full duration of cell formation. This is especially true for products that are comprised primarily of lab grown cells.

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.

See answers to questions 2b and 4.

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?

No. Terms such as pork loin, ribeye, chicken breast, etc., have specific meaning for consumers. Applying terms such as these to cell cultured products is inherently misleading and detrimental to the very industry that has established these products as popular foods.

a. If so, is additional qualifying language necessary? What qualifying terms or phrases would be appropriate?

Not applicable.

b. Do these names, with or without qualifying language, clearly distinguish foods comprised of or containing cultured animal cells from slaughtered products?

No. The use of these terms established by common usage, with or without qualifying language, dilute the meaning of these terms. Permitting new, substantially different products to compete with preexisting products utilizing the name and reputation established by the preexisting product is manifestly unfair and damaging.

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?

Terms that inaccurately communicate that the product is a particular cut of meat or poultry or produced using a particular preparation technique should not be permitted. For instance, a cylindrical lab grown product should not be labeled a bratwurst.

a. Under what circumstances should these terms be used?

Under no circumstances should inaccurate terms be allowed on labels of lab grown food products.

b. What information would these terms convey to consumers?

Not applicable.

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?

The FSIS should strongly consider establishing a regulatory standard of identity. Promulgating a standard of identity for cell cultured food products will provide both industry and consumers with consistency across all product labels.

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

The standard of identity for cell cultured food products should define these products in accordance with their production techniques. This standard should encapsulate products that originated from animal cells that have been subjected to a growth medium which resulted in artificial cell formation.

Compliance should be verified in accordance with federal law and via the methods developed and implemented by the USDA for existing standards of identity, including facility inspections.

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.

For products that meet the standard of identity, terms such as “cell cultured”, “cell cultivated”, “lab grown” and “non-meat or poultry animal product” should be considered. For products that do not meet the standard of identity, more generic terms such as protein rich food product should be considered. Terms associated with traditional meat and poultry products should be disallowed in both instances.

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.

The primary benefit to industry is consistency across various products. This is advantageous to all reasonable and fair-minded actors in the food production sector. A clear standard of identity will allow cell cultured products to compete on a level basis with meat and poultry products. In contrast, regulatory ambiguity would incentivize the use of intentionally conflating terms on food product labels.

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

Establishing a standard of identity will allow consumers to differentiate cell cultured food products from other products. A clear standard of identity enables consumers to make purchasing decisions based upon the facts rather than uncertainty facilitated by regulatory inaction.

There are no costs to consumers associated with establishing a standard of identity for cell cultured food 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 previously stated, the nutritional and health characteristics of lab grown food products are not fully understood. While there may be similarities on a molecular level, it is unlikely that these artificial products will be able to fully replicate the characteristics of natural products, especially their organoleptic characteristics. Meat and poultry can be imitated but not replicated by cell cultured 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?

Yes. The regulatory definitions for "meat", "meat byproduct" and "meat food product" should be amended to explicitly exclude lab grown products from these definitions.

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?

Yes. The regulatory definitions for "poultry product" and "poultry food product" should be amended to explicitly exclude lab grown products from these definitions.

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?

Yes. In order to allow consumers to make educated decisions about their nutrition, they must be informed of the content of the food they are consuming.

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?

Yes. Foods containing lab grown products should be labeled as such. Qualifiers such as "contains cell cultured products" should be considered.

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?

Unproven or false nutritional, animal welfare and environmental claims are likely and predictable. Absent reasonable regulation, claims improperly associating these products with our nation's storied agricultural tradition are also probable. The FSIS should consider a robust response given the high likelihood of dubious claims regarding lab grown products.

Again, thank you for the opportunity to comment on these important topics. As public servants, we can never forget our solemn responsibility to assist – not harm – those that we have been called to serve. We must remember that regulatory decisions can have far reaching consequences not only for America's farm and ranch families but for consumers and the entire economy. I urge you to approach this subject with significant caution, and to take heed of the words that appear below the seal of the USDA: "Agriculture is the Foundation of Manufacture and Commerce."

Sincerely,

A handwritten signature in blue ink, appearing to read "M. Michael Rounds", with a stylized flourish at the end.

M. Michael Rounds
United States Senator