

## USDA Opens Comment Period for Labeling Requirements for Cell-Cultured Meat and Poultry Products

Article By:

Alan J. Sachs

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On September 3, 2021, the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) opened a comment period in advance of a [proposed rule](#) on labeling requirements for meat and poultry products comprised of, or containing, cultured cells derived from animals. Stakeholders are invited to comment on specific issues that FSIS is considering for labeling these new-to-market products, including whether and how these products differ in nutritional, organoleptic (e.g., appearance, odor, taste), biological, chemical, or other characteristics from traditional meat and poultry products. Comments must be submitted by November 2, 2021.

Cell-cultured, or laboratory-grown, meat and poultry, are products that are derived from animal cells that have been biopsied or otherwise removed from animals, then grown in sterile laboratory environments and manipulated to mimic meat products from traditionally slaughtered animals. These novel products have not yet faced federal labeling requirements, though they are the subject of increased agency and stakeholder discussion and debate[1]. USDA's recent request for comment on this Advanced Notice of Proposed Rulemaking (ANPR) follows a [joint agreement](#) to oversee and regulate the production of these foods entered into by the U.S. Food and Drug Administration (FDA) and FSIS on March 7, 2019. It also follows FDA's October 2020 [request for comment](#) on the labeling of cell-cultured seafood products.

FSIS is requesting comments for this ANPR to gain stakeholder perspectives on how to best avoid misbranding of these novel products – and thereby misunderstanding among consumers. FSIS recognizes that consumers have not had experience reading labels for products containing cell-cultured meat or poultry; similarly, the industry has not yet been introduced to labeling requirements for these products. FSIS cautions that labels for these new products must present terms that are likely to be understood by the ordinary individual under customary conditions of purchase and use. Because cell-cultured meat and poultry labels will likely have “special statements or claims” that are not defined by regulation or policy, they must undergo FSIS's review and approval process. According to FSIS, any cell-cultured meat or poultry product that would be distributed before this rulemaking is finalized will require individual review. FSIS also cautions that labels approved for these products may need to be changed following the issuance of a final rule on labeling requirements.

FSIS is requesting public comment on 14 specific issues, including:

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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?*
  
  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”)?*
  
  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?*
  
  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.*
  
  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.*
  
  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?*
  
  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?*
  
  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?*

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- 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?*
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?*
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?*
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?*
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?*
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?*
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?*

86 Fed. Reg. 49495 (Sept. 3, 2021).

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[1] See, e.g., <https://www.bdlaw.com/publications/a-burger-by-any-other-name/>.

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