



**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Chapter III**

**[Docket No. FSIS-2020-0036]**

**RIN 0583-AD89**

**Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is publishing this 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 subject to the Federal Meat Inspection Act or the Poultry Products Inspection Act. Issues raised in the comments submitted in response to this ANPR will inform future rulemaking to establish labeling requirements for these products. This ANPR also discusses how FSIS will generally evaluate labels for these products if they are submitted before the Agency completes rulemaking.

**DATES:** Submit comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** FSIS invites interested persons to submit comments on this document. Comments may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** This website provides the

ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

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

- **Hand- or courier-delivered submittals:** Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350-E, Washington, DC 20250-3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2020-0036. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call (202)720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:** Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This ANPR concerns the labeling of meat and poultry products produced using animal cell culture technology, including how these products are to be identified and described specifically in regard to their nature, source, or characteristics. Animal cell culture technology is a process that involves taking a small number of cells from living animals and growing them in a controlled environment to create food, among other things. Scientists typically start with a sample of cells from the tissue of an animal, some of which are selected, screened, and stored for future use. Later, some of these stored cells are retrieved and placed in a controlled environment with appropriate nutrients and other factors to support growth and cellular multiplication. After the cells have multiplied, additional inputs such as growth factors, new surfaces for cell attachment, and additional nutrients are added to the controlled environment to enable the cells to differentiate into various cell types. Once produced, the harvested cells can be processed, packaged, and marketed in the same, or similar, manner as slaughtered<sup>1</sup> meat and poultry products. This ANPR refers to such foods as "cultured" meat and poultry products or as products compromised of or containing "cultured" animal cells. The use of this term, however, is not intended to establish or suggest nomenclature for labeling purposes.

Many companies, both domestic and foreign, are currently developing cultured products derived from the cells of food

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<sup>1</sup> This ANPR refers to all meat or poultry products not produced using animal cell culture technology as "slaughtered" meat and poultry products.

animals amenable to the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 et. seq.) (cattle, sheep, swine, goats, and fish of the order Siluriformes, e.g., catfish) or the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 et seq.) (chickens, turkeys, ducks, geese, guineas, ratites, and squabs). Human food products derived from these species (hereinafter "meat and poultry products") fall under FSIS jurisdiction. Under the FMIA and PPIA (hereinafter "the Acts"), FSIS regulates the labeling of all meat and poultry products under its jurisdiction to ensure such products are not misbranded (21 U.S.C. 607(d) and 457(c)). FSIS is now seeking comments to inform future regulatory requirements for the labeling of cultured meat and poultry products intended to prevent misbranding.

*A. FSIS Authority Over the Labeling of Cultured Meat and Poultry Products*

FSIS is the federal agency that, under the authority of the Acts, protects public health by ensuring that meat and poultry products are wholesome, not adulterated, and properly marked, labeled, and packaged. To that end, FSIS issues and enforces federal regulations to ensure, among other things, that meat and poultry products in commerce within the United States are not misbranded (21 U.S.C. 607(d) and 457(c)). With limited exceptions, U.S. states or territories may not impose requirements within the scope of the Acts—such as labeling requirements—that are in addition to, or different from, the requirements established by the Acts or their implementing regulations (21 U.S.C. 678 and 476e).

## *B. Relevant Misbranding Provisions Under the Acts*

Under the Acts, a meat or poultry product is misbranded under a number of circumstances. In general, it is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 601(n) (1) and 453(h) (1)). It is also misbranded if it is offered for sale under the name of another food (21 U.S.C. 601(n) (2) and 453(h) (2)) or if it is an imitation of another food, but not labeled as such (21 U.S.C. 601(n) (3) and 453 (h) (3)).

A product is also misbranded if it purports to be or is represented as a food for which a standard of identity has been prescribed, without conforming to the standard (21 U.S.C. 601(n) (7) and 453(h) (7)). FSIS has authority to establish standards of identity for meat and poultry products to help ensure such products have the characteristics expected by consumers (21 U.S.C. 607(c) and 457(b)). Standards of identity establish specific names, terms, and information to be used on product labels. Standards may also require the presence of certain expected ingredients in products, regulate the minimum or maximum amount of ingredients in products, or specify how products are formulated, processed, or prepared.

If a product is not covered by a standard of identity, it is misbranded unless its label bears the common or usual name of the food, if there is one, and the common or usual name of its ingredients (21 U.S.C. 601(n) (9) and 453(h) (9)). Common or usual names are generally established by common usage but, in some cases, they may be established by regulation. In the absence of

either a standard of identity or appropriate common or usual name, the product must be identified by a descriptive name (9 CFR 317.2(e) and 381.117(a)).

Words or statements that are required to appear on product labeling must be in terms likely to be understood by the ordinary individual under customary conditions of purchase and use (21 U.S.C. 601(n)(6) and 453(h)(6)). In some instances, FSIS may require qualifying language to appear on product labels when necessary to ensure product names are not misleading. For example, a product identified as a "turkey-ham," must be qualified with the statement "cured turkey thigh meat" (9 CFR 381.171).

### *C. FSIS Evaluation of Product Labels*

To prevent misbranded products from entering commerce, the Acts require FSIS to approve meat and poultry product labels before they may be used in commerce (21 U.S.C. 607(d) and 457(c)). To that end, FSIS implements a prior approval program for labels used on meat and poultry products (9 CFR part 412). Under the program, labels that bear only mandatory labeling features<sup>2</sup>, otherwise comply with the Agency's labeling regulations, and bear only claims that are defined in the regulations or are factual statements not considered a special statement or claim, are deemed "generically approved" and, thus, not subject to FSIS review before entering commerce. These

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<sup>2</sup> There are up to eight mandatory label features for each product label: (1) product name, (2) inspection legend and establishment number, (3) handling statement, (4) net weight statement, (5) ingredients statement, (6) address line, (7) nutrition facts, and (8) safe handling instructions.

labels are, however, subject to periodic compliance verification by FSIS inspectors in the field (FSIS Directive 7221.1, *Prior Labeling Approval*).

FSIS must review and approve all other labels before they are used on products intended for distribution in commerce. This includes labels that display special statements or claims.<sup>3</sup> Special statements or claims include those not defined by regulation or policy, organic claims, health claims, ingredient and processing method claims, structure-function claims, animal-raising claims, and instructional or disclaimer statements concerning pathogens (9 CFR 412.1(e)).<sup>4</sup> Establishments must provide FSIS with documentation and data to support special statements and claims for Agency review, or the labels will not be approved.

The labels for cell cultured products under FSIS jurisdiction will be subject to premarket review under the same process as other special statements or claims. This will ensure that labeling for products developed using cell culture technology are not false or misleading, that labeling requirements are applied consistently as these novel products enter the marketplace, and that the label provides the necessary product information for consumers to make informed purchasing decisions. FSIS has provided for generic approval of labeling

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<sup>3</sup> Other types of labels that require prior review include labels for religious exempt products, labels for export with deviations from domestic labeling requirements, and labels for temporary approval (9 CFR 412.1(c)).

<sup>4</sup> On September 14, 2020, FSIS published the *Prior Label Approval System: Expansion of Generic Label Approval* proposed rule, which proposes amendments to the generic labeling and special statements and claims provisions of 9 CFR part 412. (85 FR 56538).

features, statements, and claims based on demonstrated prevalent industry understanding of the effective application of those features, statements, or claims and consumer understanding of labeling statements. No widespread industry understanding of the labeling requirements for cell cultured meat and poultry products currently exists. Similarly, consumers have not yet had experience reading these types of labels.

*B. Evaluating the Need for New Labeling Requirements*

FSIS has established numerous labeling requirements for meat and poultry products in response to, among other things, the advent of new methods of production. In assessing the labeling of meat and poultry products developed using new methods or technologies, the Agency typically focuses on the biological, chemical, nutritional, and organoleptic characteristics of the finished product. The statutory and regulatory definitions of meat and poultry are also pertinent.

Pursuant to 9 CFR 301.2, the term "meat" refers to the muscle of amenable livestock that is skeletal or found in the tongue, diaphragm, heart, or esophagus, with or without the bone, skin, sinew, nerve, and blood vessels, which normally accompany such tissue and are not separated from it in the process of dressing. Meat does not include the muscle found in the lips, snout, or ears, or significant portions of bone or related components, or any amount of brain, trigeminal ganglia,

spinal cord, or dorsal root ganglia.<sup>5</sup> Any part of amenable livestock that is capable of use as human food, but does not qualify as "meat," is a "meat byproduct." Any article capable of use as human food that is made wholly or in part from any meat or other portion of amenable livestock is a "meat food product" (21 U.S.C. 601(j)).

Regarding poultry, the PPIA and its implementing regulations define the term "poultry product" as any poultry carcass or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof (21 U.S.C. 453(f); 9 CFR 381.1). The term "poultry food product" refers to any product capable of use as human food which is made in part from any poultry carcass or part thereof (9 CFR 381.1).

If a new method of production or processing alters the biological, chemical, nutritional, or organoleptic properties of meat or poultry to the extent that the resulting product no longer aligns with consumers' expectations, FSIS establishes new label requirements to ensure consumers' expectations are met. For example, in 1995, FSIS evaluated the need to establish new labeling requirements for mechanically separated poultry (MSP) (60 FR 55962, November 3, 1995). FSIS found that this novel method of deriving poultry products using the mechanical separation process resulted in a product whose physical form,

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<sup>5</sup> Specified risk materials (SRMs) are inedible and must be removed from all cattle presented for slaughter in accordance with 9 CFR 310.22. SRMs include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from cattle 30 months of age and older (9 CFR 310.22(a)(1)). SRMs also include the distal ileum of the small intestine and the tonsils from all cattle (9 CFR 310.22(a)(2)).

texture, and ingredients, e.g., bone content, differ materially from those of other boneless poultry products produced by hand deboning techniques. FSIS therefore established a new standard of identity for MSP (9 CFR 381.173) to ensure consumer expectations are met.

Conversely, in 2004, FSIS evaluated the need to establish new labeling requirements for meat derived using advanced meat recovery (AMR) systems (69 FR 1874, January 12, 2004). There, FSIS found that AMR product was comparable to meat derived by hand deboning in terms of its composition, appearance, and texture so long as it was produced in accordance with the regulations. FSIS therefore did not need to establish new labeling regulations for AMR products to meet consumer expectations. Instead, the Agency set compositional criteria for AMR products and modified the definition of "meat" to make it clear that boneless meat products, such as AMR products, may not include a significant portion of bone or related components (9 CFR 318.24).

*C. FDA-FSIS Joint Agreement Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*

On March 7, 2019, the Food and Drug Administration (FDA) and FSIS signed a 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>6</sup> The agreement describes each agency's intended role with respect to the oversight of such products. In summary, FDA will oversee the collection, growth and differentiation of livestock and poultry cells until cell harvest. A transition from FDA to FSIS oversight will occur during the cell harvest stage. FSIS will then oversee the processing, packaging, and labeling of the resulting meat and poultry products made using animal cell culture technology.

FDA will continue to have the sole responsibility to regulate foods for animals, as well as for those foods for humans comprised of or containing cultured animal cells from species under FDA's jurisdiction, i.e., those not amenable to the FMIA or PPIA, such as seafood species other than Siluriformes fish.<sup>7</sup> In the formal agreement, FSIS and FDA have agreed to develop joint principles for product labeling and claims to ensure that FDA and FSIS regulated products are labeled consistently and transparently and work developing those principles is continuing. On October 7, 2020, FDA published a Request for Information (RFI), similar to this ANPR, soliciting comments on the labeling of seafood products under their jurisdiction and made using animal cell culture technology

*(Labeling of Foods Comprised of or Containing Cultured Seafood*

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6 Formal agreement between the U.S. Department of Health and Human Services Food and Drug Administration and U.S. Department of Agriculture Office of Food Safety Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species, March 7, 2019, available at [https://www.fsis.usda.gov/sites/default/files/media\\_file/2020-07/Formal-Agreement-FSIS-FDA.pdf](https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Formal-Agreement-FSIS-FDA.pdf)

7 FDA also has jurisdiction over products with 3% or less raw meat or less than 2% cooked meat or poultry meat.

*Cells; Request for Information; 85 FR 63277*). FSIS will consider comments submitted in response to FDA's RFI as it develops rules governing the labeling of cell cultured products, to the extent they are relevant to the development of joint labeling principles and the regulation of meat and poultry.

#### *D. United States Cattlemen's Association Petition*

The United States Cattlemen's Association (USCA) filed a petition dated February 9, 2018, with FSIS regarding the labeling of cultured meat.<sup>8</sup> The petition requests that FSIS limit the definition of "beef" to products derived from cattle born, raised, and harvested in the traditional manner, and thereby prohibit foods comprised of or containing cultured animal cells from being labeled as "beef." The petition similarly requests that FSIS limit the definition of "meat" to the tissue or flesh of animals that have been harvested in the traditional manner, and thereby prohibit foods comprised of or containing cultured animal cells from being labeled as "meat."

FSIS received over 6000 comments<sup>9</sup> on the petition from trade associations, consumer advocacy groups, businesses operating in the meat, poultry, and cultured food product markets, and consumers. Most comments opposed the petition overall; however, nearly all generally agreed that cultured meat and beef should be labeled in a manner that indicates how it was produced and differentiates it from slaughtered meat products.

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<sup>8</sup> Petition 18-01 Submitted by the U.S. Cattlemen's Association, February 9, 2018, available at <https://www.fsis.usda.gov/federal-register/petitions/petition-limit-definition-beef-traditional-sources>.

<sup>9</sup> Public comments on Petition 18-01 are available at <https://www.regulations.gov/document/FSIS-2018-0016-0001/comment>.

Several commenters, both for and against the petition, discussed the nature and source of cultured meat to support their arguments. Generally, commenters in support of the petition argued that cultured meat will not have the same characteristics as slaughtered meat or beef and, thus, should not be marketed as such. Commenters opposed to the petition, however, noted that cultured meat is derived from the same species as slaughtered meat and beef and can be produced with substantially similar characteristics as such products. Many commenters opposed to the petition also argued that the terms "meat" and "beef" were necessary to inform consumers of the texture, shape, and function of certain cultured meat products.

Commenters in support of the petition typically favored the creation of a standard of identity to differentiate slaughtered meat and beef from cultured products. Some livestock industry organizations that opposed the petition overall, also supported the creation of a standard of identity for cultured meat products. However, most opposed to the petition argued that standards of identity are not warranted, based on their assertions that cultured products, like slaughtered products, fall within the statutory and regulatory definitions of "meat" or "meat food product" under the FMIA.

Finally, some commenters expressed concern that the petition, if granted, would hamper innovation and, thereby, hurt the meat industry. A few others opposed the petition contending that the regulation of cultured meat labeling would violate the

First Amendment.

*E. Public Meeting on Animal Cell Culture Technology*

FSIS and FDA held a joint public meeting in October 2018 to discuss the potential hazards, oversight considerations, and labeling of cultured food products derived from livestock and poultry tissue (83 FR 46476). The aforementioned USCA petition was also a topic of discussion. Transcripts of the meeting are available on the FSIS website.<sup>10</sup>

FSIS received approximately 315 comments on the joint public meeting, many of which were concerned with the labeling of cultured meat and poultry products. Comments expressed divergent views on whether cultured meat products should be labeled "meat." Many felt the term would be misleading, arguing that cultured products are not produced in the same manner as, nor share substantially similar characteristics with, traditional meat. Some, however, felt it would be misleading *not* to refer to cultured products as "meat," arguing that such products are derived from the same amenable livestock and can be produced to have the same characteristics as slaughtered meat products.

Many on both sides of the issue agreed that the product name and other information on cultured meat and poultry product labels should indicate they were made using animal cell culture technology. Some also asked FSIS to establish standards of

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<sup>10</sup> USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry, October 23-24, 2018, available at <https://www.fsis.usda.gov/news-events/events-meetings/usda-and-fda-joint-public-meeting-use-cell-culture-technology-develop>.

identity for cultured products. A few commenters, however, opposed such requirements, reasoning that animal cell culture technology does not alter the basic characteristics of the foods and that a standard of identity or other new labeling rules would stifle innovation in the cultured foods industry. A few comments were also concerned that new labeling requirements would unnecessarily put cultured products at a competitive disadvantage to slaughtered products.

Commenters were also concerned with the regulation of special statements and claims on cell cultured products labels. Many comments asked FSIS to subject such claims to the same prior label approval process and oversight as slaughtered products. Others asked FSIS to establish specific guidance for such claims to ensure they are truthful and supported by sound science. A few advocated that animal cell culture technology companies be allowed to make special statements and claims about the environmental, food safety, and other benefits of their products, so long as they provide evidence to support such assertions.

*F. Harvard Law School Animal Law & Policy Clinic Petition*

FSIS also has received a petition from the Harvard Law School Animal Law & Policy Clinic dated June 9, 2020, concerning the labeling of products made using animal cell culture technology.<sup>11</sup> The petition requests that FSIS adopt a labeling

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<sup>11</sup> Petition 20-03 Submitted by Harvard Law School Animal Law & Policy Clinic, June 9, 2020, available at <https://www.fsis.usda.gov/policy/petitions/>.

approach for cultured meat and poultry products that respects First Amendment commercial speech protections. The petition specifically requests that FSIS establish a labeling approach that does not require new standards of identity and does not ban the use of common or usual meat or poultry terms or other product terms specified in regulatory standards of identity. The petition asserts that FSIS should wait until the Agency has a better understanding of the compositional and safety characteristics of finished products made using animal cell culture technology, and until it has had the opportunity to review proposed labels, before establishing speech restrictions that could raise constitutional questions. To date, FSIS received one comment from a non-profit organization, conveying broad support for the petition.

#### G. U.S. Government Accountability Office Report

The U.S. Government Accountability Office (GAO) recently completed a review to, in part, understand how much information on the commercial production of cultured meat and poultry is available to federal regulators, including FSIS.<sup>12</sup> It found that federal regulators lack specific information on the technology being used, eventual commercial production methods, and composition of the final products. FSIS hopes to receive such information in response to this ANPR, so that it can make informed decisions regarding the labeling of these products.

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<sup>12</sup> U.S. Government Accountability Office, *Food Safety: FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat*, April 2020, available at: <https://www.gao.gov/products/gao-20-325>.

## II. Issues for Comment

FSIS invites comment on the issues discussed in this ANPR to help inform future rulemaking on the labeling of products made using animal cell-culture technology. Specifically, FSIS seeks responses to the questions listed below. Please explain the reasoning behind your responses in detail. Also, provide any data, studies, or other evidence that supports your response. To help FSIS review comments efficiently, please identify the question to which you are responding by its associated number and letter (e.g., "2a") or whether you are commenting on a topic not listed below.

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?
  - 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 sub-listing, 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?

### **III. Request for Economic Data and Consumer Research**

Along with the above questions about the costs and benefits of labeling options for cell cultured meat and poultry, FSIS seeks economic data and consumer research to help increase its understanding of the animal cell culture technology industry and related issues regarding labeling and consumer perceptions of food made using this technology. FSIS is particularly interested in information regarding: (1) The impact of the labeling of cell

cultured meat and poultry on consumers' perception of and willingness to pay for cultured meat and poultry products; (2) the expected price per pound of cultured meat and poultry products; (for example, FSIS has reviewed recent studies that discuss consumer perception<sup>13</sup> and willingness to pay<sup>14</sup> for cultured meat products); (2) the expected price per pound of cultured meat and poultry products; (3) the number of domestic and the number of international animal cell culture technology companies estimated to enter the U.S. market (for example, FSIS is aware of eight domestic companies who belong to the Alliance for Meat, Poultry and Seafood Innovation (AMPS Innovation) trade association); (4) the expected average annual volume per company, broken down by species or product type; (5) the expected number of labels per company, broken down by species or product type; (6) company size by expected revenue and number of employees; (7) data on the consumer benefits from labels that clearly identify or differentiate cultured meat and poultry products (e.g., saved research costs); and (8) information on naming conventions that would discourage consumer purchases or producer innovations and the associated economic impact. FSIS also seeks consumer research related to labeling nomenclature for products made using animal cell culture technology.

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<sup>13</sup> Kantor, Bella Nichole, Kantor, Jonathan. *Public Attitudes and Willingness to Pay for Cultured Meat: A Cross-Sectional Experimental Study*. *Frontiers in Sustainable Food Systems*. Volume 5 (2021) pg 26. Accessed on June 22, 2021: <https://www.frontiersin.org/articles/10.3389/fsufs.2021.594650/full>

<sup>14</sup> Rolland NCM, Markus CR, Post MJ. *The Effect of Information Content on Acceptance of Cultured Meat in a Tasting Context*. *PLOS ONE* 15(4): e0231176(2020) Accessed on June 22, 2021: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0231176>

#### **IV. Label Evaluation Prior to Rulemaking**

Should any establishment wish to distribute a cultured meat or poultry product in commerce prior to related labeling rulemaking being completed, the establishment would need to submit the product label to FSIS for review. To learn about the process for submitting labels to FSIS, please see the "Labeling and Label Approval" webpage.<sup>15</sup> As discussed above, labels for cultured product are not eligible for generic approval at this time because neither industry nor consumers have experience with cultured products or their labels. Therefore, FSIS will need to review and approve cultured meat and poultry product labels before they are used in commerce to ensure they are not false or misleading. During label review, FSIS will ensure the labels clearly differentiate cell cultured product from slaughtered meat and poultry products and will ensure the labels bear all mandatory features required by the regulations for meat and poultry products. Labels approved for cell cultured meat and poultry products prior to the conclusion of this rulemaking may need to be changed for compliance with the requirements of final regulations.

#### **V. USDA Non-Discrimination Statement**

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and

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<sup>15</sup> FSIS Labeling and Label Approval webpage, <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling>.

institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at <https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint> and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400

Independence Avenue, SW, Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: [program.intake@usda.gov](mailto:program.intake@usda.gov).

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## **VI. Additional Public Notification**

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>.

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**Paul Kiecker**  
*Administrator.*

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