



UPSIDE Foods

December 2, 2021

Administrator Paul Kiecker
United States Department of Agriculture
Food Safety and Inspection Service
Room 2534 South Building
1400 Independence Avenue SW
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

UPSIDE Foods (“UPSIDE”) appreciates this opportunity to provide comment to the U.S. Department of Agriculture’s (“USDA”) Food Safety and Inspection Service (“FSIS”), in response to the agency’s Advance Notice of Proposed Rulemaking (“ANPR”) regarding the labeling of meat and poultry products comprised of or containing cultured animal cells derived from animals subject to FSIS jurisdiction. For the purposes of this comment and as discussed further below, UPSIDE refers to these products as “cultivated” meat and poultry products.

UPSIDE is a cultivated meat, poultry, and seafood company based in Berkeley, California. We are developing real meat, poultry, and seafood directly from animal cells, without the need to raise or slaughter animals. Our mission is to better enable our food system to meet the growing global demand for animal protein products while still preserving the environment, protecting animal welfare and public health, and ensuring consumers can continue to enjoy their favorite foods. We believe that our innovative technology – along with conventionally-produced meat, poultry, and seafood – will help ensure that our food system is more diversified and equipped to address the rising global demand for animal protein products.

UPSIDE was founded in 2015 (as Memphis Meats), when there were no other cultivated meat, poultry, or seafood companies in the world. Today, there are over seventy companies globally seeking to produce cultivated products. We have always strived to build a strong coalition of diverse interests in support of innovation in the cultivation of animal cells to produce food. This includes investors from the conventionally-produced meat, poultry, and seafood industry, as well as environmental impact investors like Bill Gates, Richard Branson, and Kimbal Musk. We are proud



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members of the International Association for Food Protection and the American Meat Science Association and are a founding member of the Alliance for Meat, Poultry and Seafood Innovation.

The labeling of cultivated meat and poultry products will be a crucial component of how our industry conveys the basic nature, essential characteristics, and value of these products to consumers. Since our founding, educating and informing consumers about our technology and products has been a priority. We believe it is essential that consumers understand the cultivated meat, poultry, and seafood production process so they can make informed purchase decisions. As FSIS notes in its ANPR, cultivated meat and poultry products are produced from the cells of livestock and poultry (i.e., food animals amenable to the Federal Meat Inspection Act or Poultry Products Inspection Act).¹ Cultivated products will be processed into or combined with other foods and marketed in the same or similar manner as slaughtered meat and poultry products. Accordingly, to ensure that consumers are adequately informed, we believe product labeling should clearly communicate the source and production process for cultivated products.

With respect to the questions posed by FSIS in the ANPR, as discussed in detail below, UPSIDE believes that the labeling of cultivated meat and poultry products should bear a product name that differentiates such products from slaughtered meat or poultry. To that end, we believe a mandatory descriptive designation would inform consumers that the product is cultivated from the cells of livestock or poultry and thus was produced in a manner that differs from the production process traditionally used for slaughtered meat and poultry.

Below, we provide responses to FSIS's specific questions.

I. Responses to Questions 1 and 2 regarding whether the product name of cultivated meat or poultry should differentiate the product from slaughtered meat or poultry, and what terms should be in the product name of a cultivated meat or poultry product to convey the nature and source to consumers

With respect to Question 1, UPSIDE believes that it is appropriate for the name of a cultivated meat or poultry product to differentiate the product from slaughtered meat or poultry. As described further below, a mandatory descriptive designation – using the

¹ USDA/FSIS, Proposed Rule: Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells, 86 Fed. Reg. 49491, 49492 (Sept. 3, 2021).



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term “cultivated” along with language noting the product is derived from the “cells” of the corresponding food animal (e.g., “from chicken cells” or “from beef cells”) – in conjunction with the product name will inform consumers of how the product was produced as well as its nature and source, in a simple and direct manner, and therefore is the best mechanism for labeling cultivated meat and poultry products.

With respect to Question 2, regarding terms that convey the nature or source of the food, UPSIDE believes that the term “cultivated” along with language noting that the product is derived from the cells of a specific food animal (hereinafter, “cultivated product descriptive designation”) should appear in conjunction with the name of a cultivated food product or ingredient to convey the nature and source of the food to consumers. As discussed further below, this descriptive designation, together with the product name, will inform consumers that the product is meat or poultry that was not slaughtered, but rather was derived from animal cells and grown into the finished meat or poultry product. The nature and other characteristics of the food, including its form and function, would be further described by other terms that will be provided on the label of the package, such as “sausage,” “fillet,” or “cutlet,” where such terms are applicable. UPSIDE also supports the use of the cultivated product descriptive designation in the labeling of a blended product that contains both cultivated meat or poultry and slaughtered meat or poultry, as long as the labeling makes clear that the product contains both cultivated and slaughtered meat or poultry ingredients. This same principle should apply to blends of cultivated meat or poultry and plant-based ingredients.

a. The cultivated product descriptive designation best describes cultivated meat and poultry products

UPSIDE has considered and studied various terms that could be included in the product name of cultivated meat and poultry products, and has concluded that the cultivated product descriptive designation best achieves the goal of informing consumers of the nature, source, and production process of the product, while avoiding overly technical jargon and terms that could inadvertently denigrate slaughtered meat and poultry products. The use of such a descriptive designation is well supported by the plain meaning of the term “cultivated,” emerging consumer research, and regulatory precedent.

First, the commonly understood meaning of “cultivate” aligns with the use of the term in the product name of cultivated meat and poultry products. The term, “cultivate,” when used to describe a biological process means to “[g]row or maintain (living cells or



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tissue) in culture,” such as “All cell lines were cultivated under conditions recommended by the supplier.”² Other sources provide similar definitions of “cultivate.”³

Second, current consumer research supports use of the term “cultivated” in product labeling, especially when provided alongside language noting that the product is derived from the “cells” of a specific food animal, as a means of effectively differentiating cultivated products from slaughtered meat and poultry products. For example, research conducted on behalf of UPSIDE found that “Chicken (cultivated from chicken cells)” evokes accurate associations to the cultivated product, and that packaging using “Chicken (cultivated from chicken cells)” differentiated the product from slaughtered chicken products and made clear that the product is derived from the chicken cells. Another study demonstrated that consumers found the term “cultivated” to be a descriptive term. In that study, researchers tested 31 different terms by asking survey respondents to rate the terms on a scale from 1 to 5, with 1 being “not at all descriptive” and 5 being “extremely descriptive.” “Cultivated meat” received a descriptiveness score of 3.41, which was greater than the score for “cultured meat” and “clean meat,” among other terms.⁴

Third, this labeling approach provides meaningful benefits to consumers as well as industry. Most importantly, the cultivated product descriptive designation provides direct and accurate information to consumers, which will enable them to have a clear understanding of the nature, source, and production method for these products. Further, by differentiating cultivated meat and poultry products from slaughtered products as well as plant-based products, the descriptive designation enables consumers to affirmatively identify and distinguish between products and make informed purchase decisions. It also helps ensure that consumers who have sensitivities or allergies to slaughtered meat and poultry products (or seafood products) are able to clearly identify cultivated products as meat and poultry (and likewise for seafood), as these consumers would have the same reaction to cultivated products.

² Cultivate, Lexico, <https://www.lexico.com/en/definition/cultivate>.

³ See, e.g., Cultivate, Collins, <https://www.collinsdictionary.com/us/dictionary/english/cultivate> (“to grow (plants, crops, fish, etc.) from seeds, bulbs, shoots, etc.”); Cultivate, Dictionary.com, <https://www.dictionary.com/browse/cultivate> (“to produce by culture: *to cultivate a strain of bacteria*”); Cultivate, Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/cultivate> (“to grow or raise (something) under conditions that you can control”).

⁴ Cellular Agriculture Nomenclature: Optimizing Consumer Acceptance, Appendix E at 24 (updated Jan. 2020), The Good Food Institute, <https://gfi.org/images/uploads/2020/01/Jan-2020-Updated-2018-Cellular-Agriculture-Nomenclature-Report.pdf>.



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And, by using terminology that is accurate and objective and does not denigrate cultivated or conventional product categories, the approach allows the industry to grow and innovate without disparaging other products. Notably, various media outlets representing different audiences and stakeholders have already begun using the term “cultivated” to refer to the category.⁵

While we understand the potential use of the term “cultured” to refer to these products, UPSIDE prefers “cultivated” because “culture” and “cultured” have been used in other contexts that are different from the process used to cultivate meat and poultry products. For example, several FDA standards of identity use the term “cultured” to identify dairy products that have been fermented with lactic acid-producing bacteria. The standard of identity for “cultured milk” states that it is “the food produced by culturing one or more of the optional dairy ingredients specified in [the regulation] with characterizing microbial organisms.”⁶ “Sour cream” (or “cultured sour cream”) “results from the souring, by lactic acid producing bacteria, of pasteurized cream.”⁷ Further, other “cultured” products, such as yogurt, are generally produced by converting lactose in milk to lactic acid using starter cultures, which consist of a mixture of microorganisms.⁸ These “culturing” processes are distinct from the use of animal cells to produce cultivated meat and poultry. In addition, the term “culture” is employed in other contexts, such as the use of “aquaculture” to refer to farming of certain species of seafood, which are distinguishable from the use of cells from food animals to grow meat and poultry products.⁹ Given these important distinctions, we believe “cultivated” is a better term to describe cultivated products.

b. The cultivated product descriptive designation provides a clear and direct mechanism for disclosure

⁵ See, e.g., Elisabeth Anderson and Stephen Anderson, Cultivated Meat & Seafood – Technology, Michigan State University, Center for Research on Ingredient Safety, <https://www.canr.msu.edu/news/cultivated-meat-seafood-technology>; Adele Peters, Take a Look Inside This Shiny, Industrial “Cultivated Meat” Factory of the Future, Fast Company, Nov. 4, 2021, <https://www.fastcompany.com/90692577/take-a-look-inside-this-shiny-industrial-cultivated-meat-factory-of-the-future>; Lisa M. Keefe, FSIS Kicks The Can on “Meat” Labeling Petitions, Meatingplace.com, Sept. 20, 2021, <https://www.meatingplace.com/Industry/News/Details/101296>.

⁶ 21 C.F.R. § 131.112.

⁷ *Id.* § 131.160.

⁸ See, e.g., Microbiology & Tech. of Fermented Foods 107-44 (Robert W. Hutkins ed., 1st ed. 2006) (Chapter 4: “Cultured Dairy Products”).

⁹ See 50 C.F.R. § 622.105.



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As noted above, UPSIDE supports a descriptive designation for cultivated meat and poultry products that includes the term “cultivated” along with language noting that the product is derived from the “cells” of a specific food animal in conjunction with the product name. Such a descriptive designation will provide a clear, accurate, and easily understandable labeling disclosure for cultivated products without imposing unnecessary restrictions or regulatory burdens associated with promulgating a new standard of identity or updating existing standards of identity, both of which would be premature and ill-suited to cultivated meat and poultry products.

A descriptive designation is appropriate here because the production process is a characterizing feature of cultivated meat and poultry products, particularly when compared with slaughtered meat and poultry. Moreover, cultivated meat and poultry products may not be visually or otherwise readily distinguishable from slaughtered meat and poultry products by a consumer. In situations where FSIS has historically required a specific descriptive designation regarding a production process or other aspect of a product, the agency likewise has described that process or characteristic as a “characterizing feature” of the product that is material to consumers’ purchasing decisions or has focused on consumers’ inability to distinguish between products without a labeling disclosure.¹⁰

II. Response to Question 4 regarding what terms, if used in the product name of a cultivated food, would be potentially false or misleading to consumers

UPSIDE believes that certain terms could be false or misleading with respect to cultivated products. Specifically, UPSIDE objects to the following terms, for the reasons described below:

¹⁰ See USDA/FSIS, Proposed Rule: Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products, 78 Fed. Reg. 34589, 34592 (June 10, 2013) (FSIS concluded that mechanical tenderization “is a characterizing feature of the product and, as such, a material fact that is likely to affect consumers’ purchase decisions and that should affect their preparation of the product”); USDA/FSIS, Final Rule: Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions, 79 Fed. Reg. 79044, 79044 (Dec. 31, 2014) (FSIS “determined that some added-solution product labels that follow current labeling guidance and comply with current regulations are misleading because they do not clearly and conspicuously show that the product contains an added solution, and that, without updated labeling regulations that require the conspicuous labeling of the added solution, consumers likely cannot distinguish between raw single-ingredient products versus similar raw products containing added solution.”).



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- “Lab-based” or “Lab-grown.” Most, if not all, foods produced in a modern food system are designed, tested, or otherwise analyzed in a laboratory setting. At the stage of large-scale production, however, such foods will be produced or grown in a food production facility. This progression from laboratory setting to modern food production facility is similar to that of many other food products, such as beer, yogurt, and dairy products. Accordingly, “lab-grown” as a labeling term only for cultivated meat and poultry would be misleading, as cultivated products will not, in fact, be produced in a lab; they will be produced in food facilities that use modern science and technology to ensure safe and consistently-produced products. Therefore, calling cultivated products “lab-based” or “lab-grown” would only mislead consumers.
- “Synthetic.” The term “synthetic” means “noting or pertaining to compounds formed through a chemical process by human agency, as opposed to those of natural origin.”¹¹ In contrast, cultivated meat and poultry are produced using a biological process, and the finished products are composed of real animal cells, just as is the case for slaughtered meat and poultry products. Moreover, the cells are derived from an animal and contain the same components an animal cell is expected to contain.
- “Fake.” Our products are derived from animal sources and fed the same nutrients an animal would need its own cells to consume in order to thrive. “Fake” is an overtly disparaging term that would mislead consumers as to the nature of our products.

III. Response to Question 5 regarding what terms, if used in the product name of a cultivated food, would potentially have a negative impact on industry or consumers

UPSIDE objects to the use of any term that portrays cultivated products as inferior to slaughtered products. The method of production, alone, is an insufficient basis upon which to state that these products are inherently better or worse than those produced using conventional methods of production, and FSIS has indicated in other contexts that labeling terms should not improperly or inaccurately disparage products.¹²

¹¹ “Synthetic,” Dictionary.com, <https://www.dictionary.com/browse/synthetic>.

¹² See, e.g., USDA/FSIS, Final Rule: Use of the Term “Fresh” on the Labeling of Raw Poultry Products, 60 Fed. Reg. 44396, 44404 (Aug. 25, 1995) (“The objective of the labeling requirements adopted in this final rule is to apprise consumers whether certain poultry products may have been partly frozen to a hard-to-the-touch state at some time. FSIS believes that such descriptive labeling should not conflict with



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UPSIDE refers to its response to Question 4, as all of the terms discussed there are both false and misleading and, for that reason, such terms have the potential to negatively impact the industry and consumers.

IV. Response to Question 6, regarding whether names for slaughtered meat and poultry products established by common usage, statute, or regulation should be included in the names or standards of identity of corresponding cultivated products

UPSIDE believes that names for slaughtered meat and poultry products established by common usage, statute, or regulation may be included in the names of cultivated meat and poultry products when accompanied by the cultivated product descriptive designation, as described above. Based on our current assessment of the technology, we expect that many, if not most, cultivated meat and poultry products will be comparable to their conventional counterparts in terms of biological, chemical, nutritional, and organoleptic characteristics and, therefore, should be able to use preexisting product names in labeling, accompanied by the cultivated product descriptive designation. For example, terms such as “hamburger,” “hotdog,” “meatballs,” “sausage,” or “chicken nuggets” could be included in the name of a cultivated product.¹³ For these and other product categories, cultivated meat and poultry products should share the same characteristics of existing slaughtered meat and poultry products and, therefore, should be permitted to use preexisting terms in the product names of the cultivated products.¹⁴ As discussed above, the use of the cultivated product descriptive designation in conjunction with such product names will effectively distinguish cultivated products from slaughtered products.

the long-established regulatory definition for ‘frozen,’ nor should it disparage the high quality, wholesome products that consumers have been purchasing for many years.”); FSIS Policy Memo 023, Labeling of Boneless Ham Products (9 CFR 317.2(b)(13)) (stating that “sectioned and formed” is no longer required on boneless ham labels because “those products conform to the public’s expectations for ham” and “consumers may be confused or misled by this terminology which seems to connote an inferior product.”).

¹³ See 9 C.F.R. §§ 319.15(b), 319.180, 319.140; USDA/FSIS Food Standards and Labeling Policy Book (Aug. 2005) (“Meatballs,” “Poultry Sausage,” “Nugget”).

¹⁴ Prohibiting use of such preexisting terms in the labeling of cultivated meat and poultry products, as a class, would raise significant constitutional issues as it would impose a broad federal prohibition against truthful and non-misleading commercial speech that is unlikely to survive scrutiny under the First Amendment. See, e.g., *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557 (1980); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228 (11th Cir. 2017).



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Where no preexisting product name applies to a cultivated product, a new or modified name, in conjunction with the cultivated product descriptive designation, may be used for the product.

V. Response to Question 7, regarding whether terms that specify the form of meat or poultry products should be allowed to be included in or to accompany the name or standard of identity of cultivated foods

In general, terms that specify the form of meat or poultry products, such as “fillet” or “patty,” should be permitted to be used as part of the name of a cultivated product, along with the descriptive designation described above, as long as the form and composition of the cultivated product is comparable to that of the slaughtered products that are permitted to use such terms.

For example, under the FSIS regulations addressing labeling of poultry, “(Kind) steak or fillet” refers to a product that “consists of a boneless slice or strip of poultry meat of the kind indicated.”¹⁵ The FSIS Food Standards and Labeling Policy Book, in turn, includes an entry for “Fillet Style,” which states: “Fillet style’ must be qualified, e.g., ‘chunked and formed,’ if the meat or poultry product is not made from a solid piece of meat or poultry. The term ‘fillet’ is defined as a solid piece of meat or poultry.”¹⁶ Accordingly, if a cultivated poultry product consists of a “boneless slice or strip of poultry,” that product could use the term “fillet,” along with the cultivated product descriptive designation, in the product’s labeling. A cultivated poultry product that is not made from a solid piece of poultry but is otherwise in the style of a fillet, could be labeled as “fillet style” along with the cultivated productive descriptive designation.

Similarly, “beef patties” “consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings,” and such products may contain binders or extenders and certain other specified ingredients “only in amounts such that the product characteristics are essentially that of a meat pattie.”¹⁷ “Chicken burgers” consist of “100 percent poultry of the kind indicated, with skin and fat not in excess of natural proportions,” but if the product contains fillers or binders, “chicken patties” is the appropriate term.¹⁸ A cultivated beef product that meets the “beef patty”

¹⁵ 9 C.F.R. § 381.162.

¹⁶ USDA/FSIS, Food Standards and Labeling Policy Book (Aug. 2005) (“Fillet Style”).

¹⁷ 9 C.F.R. § 319.15(c).

¹⁸ See *id.* § 381.160.



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definition, in that it has a comparable composition and form as the slaughtered product, should be permitted to use the term “beef patty” in the product name along with the cultivated product descriptive designation. The same holds true for a cultivated chicken product that meets the “chicken burger” or “chicken patty” definition.

VI. Response to Question 8 regarding whether FSIS should 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 cultivated foods

No. As discussed above, requiring the use of a descriptive designation is more appropriate than establishing a new standard of identity for cultivated products.

UPSIDE believes that it is premature to adopt a standard of identity for cultivated products for several reasons. First, where FSIS has established a new standard of identity or process control regulation for a category of meat or poultry products produced using a different production method, the production method has typically been used for some time in commercial settings, even though the machinery or technical aspects of production may vary across producers. For example, for mechanically separated (“MS”) products and products produced using advanced meat recovery (“AMR”) systems, both FSIS and industry were reasonably familiar with the technology and the resulting meat and poultry products by the time FSIS promulgated its regulations for MS and AMR products.¹⁹

Moreover, FSIS’s regulations for MS and AMR products set forth specific details about the production technologies as well as product composition, in line with FSIS’s understanding, which had developed over years. For example, the standard of identity for MS poultry states, in relevant part, that the product results from “mechanical separation and removal of most of the bone from the attached skeletal muscle and other tissue of poultry carcasses . . . and shall not have bone solids content of more than 1

¹⁹ See, e.g., USDA/FSIS, Final Rule: Poultry Products Produced by Mechanical Separation and Products In Which Such Poultry Products Are Used, 60 Fed. Reg. 55962 (Nov. 3, 1995) (describing mechanical separation and the regulatory history leading up to FSIS promulgating a standard of identity for mechanically separated poultry); USDA/FSIS, Interim Final Rule and Request for Comment: Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems, 69 Fed. Reg. 1874 (Jan. 12, 2004) (explaining AMR technology and the regulatory history leading up to FSIS promulgating regulations setting forth compositional criteria for AMR products).



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percent,” and for certain chickens and turkeys, the product also “shall not have calcium content exceeding 0.235 percent.”²⁰ FSIS’s regulation for AMR products sets forth detailed process controls including those pertaining to bone solids and bone marrow.²¹ In contrast, the production technology for cultivated products is continuing to evolve and advance and production processes and products may vary from company to company.

In addition, the creation of a narrow or restrictive standard of identity could inhibit the innovation and development of a nascent industry, an effect that FSIS has found to weigh in favor of *revoking* a standard of identity rather than establishing one.²² In fact, FSIS has expressed support for “[e]stablishing regulations that do not stifle innovations in food technology and allow for technological alternatives and advancements in food processing,” an approach that “would improve manufacturing efficiency and lessen costs which may be passed on to the consumer.”²³ The agency has further noted that “[i]mproved technologies may additionally benefit product quality and diversity,” and that greater diversity and lower cost of foods that “continue to meet consumer expectations would promote honesty and fair dealing in the interest of consumers and protect the public.”²⁴ In this case, a new standard of identity could potentially limit the ability of the cultivated meat and poultry industry to innovate and create improved technologies, thereby preventing some of these benefits from accruing to consumers.

For these reasons, it is simply not necessary to establish a standard of identity for cultivated products, as a class, particularly where other labeling disclosures – such as a descriptive designation – are available.

²⁰ 9 C.F.R. § 381.173.

²¹ *Id.* § 381.24.

²² See USDA/FSIS, Final Rule: Definitions and Standards of Identity or Composition: Elimination of the Pizza with Meat or Sausage Standards, 68 Fed. Reg. 44859, 44862 (July 31, 2003) (“FSIS has determined that over the years consumer expectations, industry creativity, and technological innovation have created new types of pizza products that fall outside the realm of the traditional or standardized pizza of several decades ago. The existing pizza standards inhibit the production and marketing by Federal establishments of new pizza products.”).

²³ USDA/FSIS and FDA, Proposed Rule: Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29214, 29222 (May 20, 2005). In addition, FSIS has recognized that food standards should “permit maximum flexibility in the food technology used to prepare the standardized food,” including “suitable, alternative manufacturing” methods, “so long as that technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality, or safety of the food.” *Id.* Establishing an overly restrictive standard of identity or interpreting pre-existing standards to not apply to cultivated products, as a class, would contravene these important principles.

²⁴ *Id.*



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VII. Response to Question 9 regarding 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 cultivated products

As noted above, the technology and techniques used to produce cultivated products continue to evolve and may also vary from company to company. Based on our current assessment of the technology, UPSIDE expects that many, if not most, cultivated meat and poultry products will be comparable to their conventional counterparts in terms of biological, chemical, and nutritional characteristics. Accordingly, it is difficult to draw general conclusions regarding the material characteristics of cultivated meat and poultry products at this time.

VIII. Response to Questions 10 and 11 regarding whether any of the definitions for "meat," "meat byproduct," or "meat food product" found in 9 CFR 301.2, or for "poultry product" or "poultry food product" found in 9 CFR 381.1, should be amended to specifically include or exclude cultivated foods

UPSIDE believes that the existing definitions for "meat," "meat food product," "poultry product," and "poultry food product" encompass cultivated meat and poultry products, respectively.²⁵ The FMIA and PPIA, as well as USDA's implementing regulations, contain product category definitions, including "meat," "meat food product," "poultry," and "poultry product." These definitions set forth the fundamental criteria for determining whether a product falls within the general product categories for "meat" and "poultry" products and therefore may be labeled in accordance with species- or product-specific terms (e.g., "hamburger," "beef patties," "meatballs," "pork" or "beef," "sausage," or "chicken fritters").

²⁵ UPSIDE notes that its cultivated meat products cannot be characterized as "meat byproducts" based upon the definition of that term.



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In particular, the FMIA defines “meat food product” as “any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats...”²⁶ The PPIA defines “poultry” as “any domesticated bird, whether live or dead,” and “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...”²⁷ FSIS regulations define “meat” as “[t]he part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing.”²⁸ FSIS regulations define “carcass” as “[a]ll parts, including viscera, of any slaughtered livestock” or “slaughtered poultry,” as applicable.²⁹

Accordingly, the definitions of “meat” and “poultry” products each have three fundamental characteristics: Meat is: (1) derived from certain species of livestock; (2) from a certain part of that animal; and (3) non-living. Likewise, a poultry product is: (1) derived from a domesticated bird; (2) is wholly or in part from that bird; and (3) is non-living upon consumption. Cultivated meat and poultry meet each of these respective criteria.

The first and second criteria for meat and poultry are apparent from the plain text of the statutory and regulatory definitions. For meat, the species include “cattle, sheep, swine, or goats.”³⁰ For poultry, the domesticated birds include “chickens, turkeys, ducks, geese, guineas, ratites, or squabs.”³¹ Moreover, the statutory and regulatory definitions for meat and poultry products explicitly contain the term “parts” when referring to the livestock species or domesticated birds from which the products are derived. The third criterion reflects the reality that, when meat and poultry products generally are sold to consumers, they are sold as non-living parts derived from a specific food animal. As explained by FSIS, “meat” is “essentially muscle that is skeletal

²⁶ 21 U.S.C. § 601(j).

²⁷ *Id.* § 453(e) and (f); *see also* 9 C.F.R. § 381.1.

²⁸ 9 C.F.R. § 301.2.

²⁹ *Id.*; 9 C.F.R. § 381.1.

³⁰ 21 U.S.C. § 601(j); 9 C.F.R. § 301.2.

³¹ 9 C.F.R. § 381.1.



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or found in the tongue, diaphragm, heart, or esophagus” of livestock.³² Likewise, poultry is essentially muscle or certain other parts of a domesticated bird.

Cultivated meat and poultry satisfy each of these criteria. Before the advent of cell cultivation technology, humans have had to slaughter livestock, poultry, or fish to obtain non-living tissue from animals for human consumption. Now, cells from these animals can be grown and harvested outside of the animal without the need for slaughter. The finished food product meets the criteria described above because it is derived from livestock or a domesticated bird, as applicable; it is a part of that animal; and it is non-living upon consumption. Notwithstanding that cultivated meat and poultry meet the applicable statutory and regulatory definitions as described above, UPSIDE supports amending such definitions to explicitly include cultivated products in order to provide further clarity.

IX. Response to Questions 12 and 13 regarding whether FSIS-regulated broths, bases, and reaction flavors should be required to declare the source material when produced from cultivated products and whether the presence of cultivated products in further processed products regulated by FSIS should be qualified on the product label

UPSIDE supports labeling FSIS-regulated broths, bases, and reaction flavors produced from animal cells consistent with the descriptive designation discussed above. UPSIDE also supports disclosing the presence of cultivated products in further processed products regulated by FSIS by using the descriptive designation in the ingredient declaration.

X. Response to Question 14 regarding what label claims are likely to appear on FSIS-regulated cultivated products and whether FSIS should develop new regulations or guidance on such claims to ensure they are neither false nor misleading

³² See USDA/FSIS, Proposed Rule: Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems, 63 Fed. Reg. 17959, 17959 (Apr. 13, 1998).



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Given that many companies that will produce cultivated meat and poultry are still developing their products and have not yet begun the label review process with FSIS, UPSIDE believes that it is premature to identify the label claims that may be considered or submitted to FSIS for approval. UPSIDE encourages FSIS to use the same process to review labeling claims for cultivated meat and poultry as is currently used for labeling claims for slaughtered meat and poultry, including requirements for supporting documentation. Approved claims should also be subject to existing standards, i.e., they must be truthful and not misleading and adequately supported.

* * *

UPSIDE thanks USDA for the opportunity to comment on the framework for the labeling of cultivated meat and poultry. We look forward to continuing to provide input to the agency as it develops principles for the labeling of cultivated products.

Sincerely,

Eric Schulze, PhD
Vice President, Product and Regulation
UPSIDE Foods