



December 2, 2021

U.S Department of Agriculture
Food Safety and Inspection Service
1400 Independence Ave. S.W.,
Washington, D.C. 20250

Re: Request for comment 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 (FMIA; 21 U.S.C. 601 et. seq.) or the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 et seq.)

Comments posted on Regulations.gov to:
[Docket No. FSIS-2020-0036]

To Whom it May Concern,

On behalf of the Center for Food Safety and our one million members, we appreciate the opportunity to submit comments to the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) on “Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells.”

We are joined in these comments by our partner group, Food and Water Watch.

As a nonprofit organizations working with consumers, farmers and ranchers, and others concerned with safe food and sustainable agriculture across the planet, we are concerned that foods be appropriately labeled. We do not think that a new labeling scheme should confuse consumers about what products are made from animals and which products are a blend of chemicals and animal cells produced in industrial vats.

As FSIS considers how to ensure that products comprised of or containing cultured cells derived from amenable species are truthfully labeled, we appreciate the opportunity to comment on how to best address challenges and provide recommendations to ensure fair and transparent markets for farmers and consumers.

Please find below our responses to those questions that most relate to our expertise in this sector and the potential impacts on our key stakeholders:

No products should be sold or labeled for sale if they are cultivated using fetal bovine serum, growth hormone or made into pluripotent cells using genetic sequences known to contribute to cancer development.

A number of companies are attempting to grow cells from meat and poultry in industrial-sized vats. Many of these companies are still reliant on the use of fetal calf serum to grow the cells, which is obtained by taking embryonic calves from pregnant cows. Other companies are experimenting with

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using genetic engineering to trick the cells into growing as though they are embryonic cells. This is to make them 'pluripotent' cell lines.

USDA should not allow the production of cells cultured in fetal serum from any animals or the labeling of such products.

As for genetically engineered cell lines, some of these come from genetic sequences known to cause cancer. New kinds of genetic engineering might magnify the problem. A recent study in the UK journal *Nature*, shows that in many different cell types, CRISPR gene-editing can confer a selective advantage to cells harboring mutations in genes associated with cancer, such as p53 and KRAS. It shows that when CRISPR-Cas9 is used to edit the genome, cells with cancer-associated mutations are likely to be selected to survive; and this is more widespread than scientists previously understood.ⁱ

The USDA should ban the use of those cell lines that use genes known to contribute to cancer and not permit their sale or labeling. When CRISPR-Cas9 is used to edit the genome, as it likely will be in cell cultured "meats", cells with cancer-associated mutations will likely survive.ⁱⁱ

Other kinds of genetic engineering might be considered but the product must be labeled as "genetically engineered muscle, fat, bone cells, etc. cultured from [name of animal, i.e., chicken, beef, lamb]".

All other kinds of cell cultured "meats" and "poultry" should be labeled as to include the species of animal whose cells were biopsied to make the cell line. Such as "this synthetic product is made from cultured meat, fat, bone cells extracted from beef" or "this synthetic product is made from cultured meat, fat, bone cells extracted from a chicken."

• Question 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?

Consumers are already confused by the food label claims on slaughtered meat and poultry product packaging, such as "natural," or "sustainable" which are not independently verified and lack clear definitions.

Synthetic products comprised of cultured animal cells must be clearly differentiated from slaughtered meat before they are marketed. FSIS is required to regulate the labeling of all meat and poultry products under its authority to ensure products are not misbranded. FSIS must exercise great caution to ensure that these synthetic products derived from or containing cultured animal cells are clearly labeled to avoid consumer confusion and mistrust, and to ensure consumers are able to choose which food production systems they support. A primary method for differentiation is whether the product came from a slaughtered animal or from cultured protein, fat, bone and other cells taken from livestock and poultry.

Even the term "cultured" is confusing. Consumers are used to purchasing cultured milk products such as yogurt, kefir, buttermilk, and cheeses, but might be tricked into believing these "cultured" cells were modified using friendly bacteria, not using new biotechnology techniques.

Since the 12th century, Japanese fishing communities have processed excess fish catches by mincing the fish and salting it for storage in an altered form. They do not call this product "fish", but rather by

another term--“surimi”. The surimi is then flavored to taste like more expensive shellfish but is sold as “crab surimi,” etc. so no one is confused about what it is. An unfamiliar word for synthetically “cultured” meat and poultry creations would be similarly helpful.

Consumers are increasingly interested in purchasing healthy products with known benefits for the environment, animal welfare and rural communities. Any product which did not originate from a live animal, nor born from another live animal and raised on a farm, should not be labeled as meat or poultry (or their equivalent) and should be clearly identified as a synthetic product derived from animal cell culture technology.

Consumers need Product Safety and other information in its most transparent form.

Because so many people have allergies to proteins in meat and poultry, the synthesized products should clearly indicate which animal’s cells it derives from.

The allergenicity labeling should be on the front of the product’s packaging in the same font and manner as other required allergy labels.

The label should also list all ingredients and materials used in the manufacturing process. Consumers should know both about the ingredients in the final product and the ingredients in the “soup” in which the cells are being “cultured.” Companies should not keep this information from consumers as “confidential.” Indeed, the process used for culturing the cells will become an issue for consumers as it may affect moral and health choices. The percentage of synthetic “cultured” meat and poultry cells in a product should also be on the product label. Food additives such as a genetically engineered “heme” used to make the product appear to “bleed” should also be on the product’s label.

The labeling guidance of bioengineered foods should NOT be used as a precedent. This approach that calls what the public knows as “genetically engineered” foods “bioengineered”, is already failing consumers who seek information about foods containing genetically engineered ingredients—it is inadequate, confusing, obfuscates rather than informs, and further exacerbates existing inequities in access to information which should be readily and publicly available. The regulations do not cover all genetically engineered products and allows the company selling the products to use in small type the term “bioengineered”, or to just list their website or a QR code that requires a smart phone to read.

Consumers want to know if foods are produced using genetic engineering for many reasons: health, personal, economic, environmental, religious, and cultural. For example, on the health side, many consumers know that the FDA does not independently assess the safety of GE foods or require them to be tested. That is, FDA does not “approve” GE foods for safety; instead, the FDA merely reviews the industry’s test results, and even this is not required, but proceeds on a confidential, voluntary basis, if the company chooses to consult with FDA. Market entry for GE foods is thus based solely on confidential industry research. This rightly gives consumers pause. The challenges of the bioengineered disclosure regulations are made worse by the new cell culturing technologies that the USDA and FDA had not even considered when the “bioengineered/genetic engineered food disclosure” act was passed. Challenges to the bioengineered regulation will only grow if similar approaches are permitted as the delivery mechanism for information about and labeling of cell-cultured meat and poultry products.

- **Question 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”)?

The names used for these products should clarify how different this new technology is from traditional meat and poultry products. “Synthetic cell-cultured meat and poultry product” could be the generic product name, with the product specifying which animal cells it derives from. For example, “Made with synthetic cell-cultured protein derived from bovine cells.” “Synthetic Cell-cultured” would not risk confusion with other cultured products. However, it is likely that products might contain cells from more than one species of animal. For example, you might have “synthetic cells of bovine muscle grown on a lattice of pork bone cells” if it proves easier to grow or extract cells on which the bovine muscles can grow from other species. In those cases, all species whose cells have been grown and manipulated in the development of the product need to be labeled. See below for continued discussion of this point.

• **Question 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?**

Labeling requirements should ensure that consumers can clearly identify if a meat or poultry product is comprised of both slaughtered meat or poultry and cultured animal cells, with percentages of each clearly listed and prominence on front of package according to the recommendations in these comments. It is possible that a label would read: 50 percent “traditional” beef, 40% synthetically cultured cells from bovine sources, 10% synthetically cultured pork cartilage cells.

• **Question 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.**

Terms which would be false or misleading and should be prohibited in the product name of a food comprised of or containing synthetic cultured animal cells include:

Humane --There is an established and growing market for animal products with animal welfare claims. Indeed, the President of the Center for Food Safety Board of Directors is Adelle Douglas, the CEO of Humane Farm Animal Care.ⁱⁱⁱ “Certified Humane” is the certification program of Humane Farm Animal Care. Where no animals are raised, there can be no assessment of animal husbandry. Furthermore, the animal welfare impacts of cell-cultured protein could very well be negative, making this claim potentially even more misleading on such a product. The cells of the meat and poultry that are grown in the vats are extracted initially from live animals. Again, without more information about whether the donor animal suffers in this process, one cannot call it “Humane.”

Natural – Consumers have perceived this technology as “unnatural” and “lab meat “. The proponents are working hard to rebrand these technologies as natural, stating the vats in which the “culture” has

been grown are just like the vats used to make beer or yogurt. Still, most consumers would not call this way of growing meat-like products, “Natural”.

According to research by Consumer Reports^{iv}, a majority of consumers expect a “natural” claim to mean: no artificial ingredients or colors were added to the meat or poultry (65%), no artificial growth hormones were used (64%), the animals' feed contained no artificial ingredients or colors (61%), the animals' feed contained no GMOs (59%), and no antibiotics or other drugs were used (57%). A greater percentage feel this label should mean no artificial ingredients or colors were added to the meat or poultry (85%), no artificial growth hormones were used (87%), the animals' feed contained no artificial ingredients or colors (83%), the animals' feed contained no GMOs (81%), and no antibiotics or other drugs were used (82%).

As these cell cultured processes make synthetic-artificial cells and there are no prohibitions on the inputs listed, most consumers would find a “natural” claim misleading when applied to synthetic cell-cultured “meat and poultry” derived from animal cells and serums.

Organic – While “Organic” standards do not currently address cell-cultured products derived from animal cells, proponents of cell cultured meats and poultry might petition for these methods to become certified as “Organic”. Groups like the Center for Food Safety would argue that these methods, especially those that rely on fetal serum or genetic engineering of cell lines are already covered under the “excluded methods” for organic production. These artificial meats and poultry products would be contrary to the spirit and goals of organic production. Synthetic cell cultured meat and poultry products would constitute the antithesis of “Organic”. “Organic” is defined by the National Organic Standards Board as “an ecological production management system that promotes and enhances biodiversity, biological cycles and soil biological activity,” Organic production is intended to be based on “minimal use of off-farm inputs and on management practices that restore, maintain and enhance ecological harmony.” Artificial Cell-cultured “meat and poultry products” derived from animal cells, produced in a tightly controlled laboratory or factory environment, would fail any reasonable expectation of what organic means. The USDA and the National Organic Program should aggressively oppose any organization trying to certify these products as “Organic”.

Sustainable – There is no evidence that synthetic cell-cultured “meat/poultry” products derived from animal cells is “sustainable” by any measure. The energy needs alone of running industrial scale vat production systems likely make it significantly more resource-intensive than, for instance, small scale/non CAFO farms with cattle grazing established pasture.

Breed claims—The names of breeds are controlled by the breeding associations. No one can claim that their beef is “Angus” unless an Angus breed group certifies the pedigree of that animal. Thus, no one should be able to take cells from an Angus, Red Devon, Long Horn or any other pedigreed animals and claim that they are that breed. Because no animals were used for anything other than to source the cells that were synthetically grown, the cell cultured industry should not be allowed to claim their “beef” comes from a particular breed. Breeds have been developed through careful breeding over many generations. FSIS already prohibits many animal rearing claims^v, they should enforce them on these products too.

Question 5: What term(s), if used in the product name of a food comprised of or containing cultured animal cells, would potentially have a negative impact on industry or consumers? For each term, please provide your reasoning.

Please see above comments on natural, humane, sustainable, organic and breed claims. Consumers expect the government to enforce the language of such claims. Farmers, ranchers, processors and other producers offering validated claims from the above list would be negatively impacted by lost markets and unfair competition.

Popular claims such as “Natural,” “Sustainable,” or “Humane” are already widely misunderstood and rarely independently verified. Producers who are genuinely delivering these attributes, like those certified by Certified Humane, A Greener World, and the National Organic Program certifiers are already at a disadvantage due to misleading marketing, or “greenwashing” by producers who promise sustainability rather than delivering it. Synthetic “cell cultured meat and poultry” is the latest step in the hype industrialization of agriculture. It is intended to undermine the real sustainable farmers and to replace them with industrial “meat” plants.

Question 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?

The common names or standards of identity of such products derived from cultured animal cells should NOT include names for products established by common usage. Names of various cuts of meat automatically include the physical and anatomical structures of the cut. That is the amount of fat, the structure and “mouth feel” of the cut. These attributes will not be found in the synthetic cell cultured forms. Using the common terms like loin, flank steak, T-bone, etc. would constitute a kind of consumer fraud.

Question 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?

Some of these terms that do not specify a particular cut of meat or part of a bird might be allowed in a minimalist way. The term “fillet” however should not be used as it indicates a cut of meat or poultry was carved off a bone or bones, a process not possible in the synthetic cell cultured meat or poultry product.

One such label might read:

Synthesized or imitation “burgers” made from cell-cultured meat [or poultry] cells from cows [or turkeys]

This should be in large fonts on the front of the package and on the nutrition panel of the product.

Question 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?

Given we do not have access to the products developed by the synthetic cell cultured industry, so that we could test them for nutritional and organoleptic properties, we cannot answer questions about a potential product. We certainly suspect that the cultured form of the product that lacks a blood and nerve system that could distribute various chemicals that make up the attributes of meat and poultry would not have the same nutritional aspects as the natural form.

As Joe Fassler notes in his article “Lab-grown meat is supposed to be inevitable”^{vi} significant concerns exist about the food safety of producing cell-cultured protein safely at any scale, where sterility and biosecurity are paramount.

The trade association for the emerging cell culture industry, The Good Food Institute (GFI), promotes the success of cell cultured products as inevitable, and dismisses the comments of its critics. However, the techno-economic analysis (TEA) done by GFI^{vii}, prompted Open Philanthropy—a multi-faceted research and investment entity with a nonprofit grant-making arm, which is also one of GFI’s biggest funders—to complete a very robust TEA of its own, one that concluded cell-cultured meat will likely never be a cost-competitive food. David Humbird, the UC Berkeley-trained chemical engineer who spent over two years researching the report, found that the cell-culture process will be plagued by extreme, intractable technical challenges at food scale. Most troubling are the problems of keeping pathogens out of the reactor. Moreover, addressing the problems of pathogens may degrade the growth factors needed for the nutritional aspects of the intended food and even promote reactions that promote cancer.

Humbird^{viii} writes:

. If cells are the product, any virus introduced by raw materials will end up in said product if not removed upstream. Any retrovirus generated during culture (whether or not it is shed externally) cannot be removed at all, at least not without significantly altering or perhaps killing the cells. So, just as the errant mouse virus particle carried over from the field or warehouse might have the potential to infect an entire culture of CHO (rodent) cells, a cultured-meat bioreactor full of, e.g., chicken cells would require protection against all manner of avian viruses, particularly those that may subsequently infect the humans handling or consuming those cells, such as coronaviruses. Protection will be especially challenging when the production of raw media components including glucose and planthydrolysates is likely to be agriculture adjacent.

Media sterility safeguards include high-temperature/short-time (HTST) treatment and retention filters. The former is more cost-effective than the latter and is compatible with microbial fermentation media (sugars and mineral salts), but heat treatment may degrade the amino acids and growth factors required in animal cell-culture media. In particular, amino acids and glucose cannot be heated together, or they will undergo Maillard reactions, potentially forming carcinogenic or mutagenic compounds.

Sterility assurance also imposes a practical limit on bioreactor size, but ultimately consumer acceptance of food products made from or containing synthetic cultured cells derived from animals will be decided on additional bases. These products still derive from meat and poultry cells and consumers wanting to avoid meat have many plant-based protein options. Moreover, animals will still have to be raised for the cells used to cultivate more cells in the reactors. Consumers also seem to dislike things they view as “unnatural”. Products raised in large vats would seem to be the epitome of “unnatural” meat. Other consumers will worry about whether these products fit the food standards of their religion’s dietary laws.

Question 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?

Foods comprised of or containing cultured animal cells should be distinct from meat products at all points in the supply chain and specifically excluded from any definition of a meat product, including “meat”, “meat byproduct”, or “meat food product.” Separate definitions need to be composed for synthetic cell cultured “meat” and “poultry” products and byproducts.

Question 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?

Foods comprised of or containing cultured animal cells should be distinct from meat products at all points in the supply chain and specifically excluded from any definition of a poultry product, including “poultry product” or “poultry food product.”

Question 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?

Yes. Just as FSIS requires traceability statements for labels making animal raising claims, traceability should be upheld in the case of FSIS-broths, bases and reaction flavors produced from cultured animal cells. The source material should be clearly included on front of package according to the recommendations we indicated earlier comments in this document.

Question 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. Just as FSIS requires traceability statements for labels making animal raising claims, traceability should be upheld in the case of FSIS-regulated products containing any ingredients from cultured animal cells. Language along the lines of “Contains protein, fat and other cells made from synthetic cultured animal cells” along with the source material should be clearly included on front of package according to previous recommendations.

Question 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?

Many label claims have now been co-opted by major corporations, or where claims are used that are often misleading (such as “sustainable” or “natural”), FSIS must issue strict regulations and requirements for the use of claims for products comprised of or containing synthetic cultured animal cells.

Please see our earlier responses to previous questions for more detail on the vast range of potentially misleading food labels and our recommendations to prevent this.

Finally, products comprised of or containing synthetic cultured animal cells are processed products. They are essentially complex food additives. Unless products made from synthesized cultured animal cells are

clearly labeled – thus enabling consumers to make informed purchasing decisions – the USDA would be helping the company commit a kind of fraud on the consumer.

Thank you for considering our comments. This new industry raises serious economic and health issues for consumers. If heavily subsidized by the USDA, it will threaten farmers, ranchers and independent food producers through an unfair market in new industrial synthetic meat and poultry products.

Please contact us if we can address any additional questions.

Sincerely,

Jaydee Hanson, Policy Director, Center for Food Safety

Zach Corrigan, Senior Attorney, Food and Water Justice, a project of Food and Water Watch

ⁱ A systematic genome-wide mapping of oncogenic mutation selection during CRISPR-Cas9 genome editing <https://www.nature.com/articles/s41467-021-26788-6>

ⁱⁱ *ibid.*

ⁱⁱⁱ <https://certifiedhumane.org/>

^{iv} Consumer Reports® National Research Center. Decoding the Labels on Meat Packaging. Nationally Representative Survey, June 2016. <https://www.consumerreports.org/food/decoding-the-labels-on-meat-packages/>

^v : https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/RaisingClaims.pdf

^{vi} Fraser, Joe. (2021, Sept 19.) Lab-grown meat is supposed to be inevitable. The science tells a different story. The Counter. <https://thecounter.org/lab-grown-cultivated-meat-cost-at-scale/>

^{vii} Vergeer, Robert. (2020) CE Delft TEA of Cultivated Meat. https://cedelft.eu/wp-content/uploads/sites/2/2021/02/CE_Delft_190254_TEA_of_Cultivated_Meat_FINAL_corrigenum.pdf

^{viii} Humbird, D. (2020, December 29). Scale-Up Economics for Cultured Meat: Techno-Economic Analysis and Due Diligence. <https://doi.org/10.31224/osf.io/795su>