



12/26/2018

Paul Kiecker
Acting Administrator
Food Safety and Inspection Service
United States Department of Agriculture
Room 331-E Whitten Building
1400 Independence Avenue SW.
Washington, DC 20250-0251

Leslie Kux
Associate Commissioner for Policy
Food and Drug Administration
White Oak Building 32
Room 4232
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Docket No. FSIS-2018-0036; Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry; USDA/FDA Request for Comments

Dear Mr. Kiecker and Ms. Kux:

Initiated in 1898, the National Cattlemen's Beef Association (NCBA) is the nation's oldest and largest national trade association representing America's cattle farmers and ranchers, working to advance the economic, political, and social interests of its producer-members.

NCBA appreciates the opportunity to submit written comments in response to the October 24-25, 2018, U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) joint public meeting on the use of cell culture technology to develop products derived from livestock and poultry, and more recently, the November 16, 2018, announcement of a regulatory framework involving both USDA and FDA.

U.S. cattle producers have always been glad to compete for the center of the plate. Due to the unparalleled quality of our products, we are confident that beef will always be what's for dinner. As such, NCBA maintains an unwavering commitment to a reasonable, equitable, and science-based regulatory framework. Further, cell-cultured meat manufacturers must not be permitted to use the term "beef" or any nomenclature associated with traditional livestock production. NCBA firmly believes that the term "beef" should only be applicable to products derived from livestock raised by farmers and ranchers.



USDA oversight of cell-cultured food production and labeling protects consumers.

The regulatory framework announced by USDA and FDA is an encouraging step in the right direction. In that announcement, the agencies outlined the following breakdown of responsibilities:

“FDA oversees cell collection, cell banks, and cell growth and differentiation. A transition from FDA to USDA oversight will occur during the cell harvest stage. USDA will then oversee the production and labeling of food products derived from the cells of livestock and poultry.”¹

Under this arrangement, USDA will shoulder the primary oversight role when it comes to the food production and labeling of cell-cultured protein products. Maintaining USDA oversight of these two functions is essential to protecting the health and well-being of consumers, and ensuring a level playing field for all producers. As NCBA has previously noted, USDA is the agency best placed to manage the substantial food safety and labeling needs of emerging cell-culture technologies.

Consumers deserve the highest food safety standards when it comes to the products they put on their families’ table. USDA’s Food Safety Inspection Service (FSIS) inspects processing facilities daily; by contrast, FDA only inspects food production facilities once every several years. Continuous, daily inspection by highly-trained professionals is a hallmark FSIS that keeps consumers safe and will help ensure that cell-cultured and conventional products are treated equally. Under FSIS oversight, any product purporting to be a meat food product will be subject to the same inspection procedures as traditional products.

Product labeling is a critically important regulatory component. In contrast to FDA’s limited labeling regime, all product labels subject to FSIS oversight must receive approval before entering the marketplace. FSIS oversight of cell-cultured product labels will help ensure claims are based on sound science and allow consumers to make an informed choice.

Manufacturers should make samples available before regulatory framework is finalized.

The preliminary agreement between USDA and FDA leaves many critical questions unanswered. NCBA is aware that the agencies are now negotiating a Memorandum of Understanding (MoU) regarding their respective oversight roles. As that process moves forward, NCBA wishes to remind the agencies of two important considerations.

First, NCBA’s view continues to be that cell-cultured protein products must meet at least one of the legal definitions, “meat,” “meat food products,” or “meat byproducts,” promulgated under the Federal Meat Inspection Act (FMIA). These terms identify distinctly different products under federal law, but all three fall under FSIS oversight jurisdiction. Manufacturers of cell-cultured

¹ U.S. Department of Agriculture, Office of the Secretary. (2018, November 16). *Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry* [Press release]. Retrieved from <https://www.usda.gov/media/press-releases/2018/11/16/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb>

proteins contend their products are specifically designed to be comparable to conventionally-produced meat products in terms of safety, composition, nutritional profile, organoleptic qualities, and function. They claim that the only difference between cell-cultured and traditional meat food products is the process by which the animal “parts” are grown and harvested. If true, any reasonable interpretation of the law solidifies FSIS’s role as the primary regulatory authority responsible for the oversight of cell-cultured meat food products.

Second, in the absence of independent, scientific evaluation of cell-cultured products, NCBA and other stakeholders have been forced to base assessments on the unverified claims of cell-culture manufacturers and the limited academic research on the topic. As Dr. Rhonda Miller, past president of the American Meat Science Association and professor and research fellow at Texas A&M, said at FDA’s first public meeting on cell-cultured products:

Meat scientists do not have enough information about cultured tissue to determine whether it should be called meat or how it should be regulated. Please note that samples of cultured tissue have not been available for evaluation of the safety, composition, nutritional bioavailability, functionality and sensory properties to understand how it compares to meat from conventional animal production.²

Until independent researchers can evaluate cell-cultured protein products, FSIS and FDA should refrain from finalizing the regulatory framework. While current sample products are proprietary and closely held, it is incumbent on cell-cultured protein manufacturers to make samples available well before products are slated for introduction into the commercial market. Only through objective analysis can the federal government, scientific community, and other stakeholders truly understand the products in question.

Manufacturers should provide adequate detail needed to assess production risks and hazards at scale.

The specific production processes and various inputs utilized throughout the cell-cultured manufacturing process have also been closely guarded by cell-cultured protein manufacturers. Although information about the research phase and general principles for cell-culture production is publicly available, the scientific community has not reached a consensus regarding the risks and hazards associated with these products, particularly when manufactured on an industrial scale.

The joint regulatory framework announcement delegated various responsibilities to each agency, but notably missing from the release was any discussion about a pre-market safety review process. Traditionally, FDA has been responsible for conducting premarket safety evaluations for various products, manufacturing inputs and production technologies alike, ranging from drugs produced through cell-culture and enzymes produced through biotechnology, to the approval of food additives and food processing technologies like irradiation. Under the Federal Food, Drug, and Cosmetic Act, it would be appropriate for FDA to

² FDA Public Meeting: Foods Produced Using Animal Cell Culture Technology. (2018, July 12). Retrieved from <https://www.fda.gov/downloads/Food/NewsEvents/WorkshopsMeetingsConferences/UCM615856.pdf>



utilize existing processes as a template to build upon. NCBA firmly believes that in addition to determining the safety of finished products, the manufacturing process and any novel substances used in cell-culture production should also be subject to stringent exposure and safety assessments.

For example, many cell-culture companies tout their products as free from antibiotics, but several industry experts and independent scientific assessments have noted quite the opposite. At the joint USDA-FDA meeting, Barbara Kowalczyk, Assistant Professor in the Department of Food Science and Technology at The Ohio State University, stated:

[Lab-grown meat products] will not be sterile. The environment where they are grown is very conducive to the growth of pathogens. One of the things I have heard...is that antibiotics are not going to be used in these products. That is not true. Antimicrobials will be used in these products. If they are produced in an aseptic environment, they have to use antimicrobials to get there. If these products are not labeled properly so that consumers know what they are getting, it's going to be misleading.³

In addition to antibiotic use, another author pointed out the following risks:

- **Presence of cancerous cells in the tissue samples.** This circumstance could occur due to genetic instability resulting from the high number of proliferations that are required to increase the cell number.
- **Unknown nutrients and chemicals in the cell growth medium.** Numerous types of nutrients, growth factors, and hormones are necessary to stimulate cell growth.⁴

The federal government can only adequately assess risks if the features of the production process are known.

FSIS should develop clear, science-based production control standards.

The chemical, physical and microbial risks and hazards associated with cell-cultured meat in some respects will likely differ from conventional meat production processes, but any product derived from livestock cells will surely be subject to similar food safety vulnerabilities that can only be addressed and mitigated through stringent FSIS oversight.

The development and adoption of science-based control standards like Hazard Analysis Critical Control Point (HACCP) plans and Sanitation Standard Operating Procedures (SSOP) is the best way to prevent problems before they occur. Further, the current FSIS regulatory system is effective because food manufacturing facilities are held accountable through daily, continuous inspection.

³ USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry. (2018, October 24). Retrieved from <https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/past-meetings>.

⁴ Hocquette, Jean Francois. (2016, October). *Is in-vitro meat the solution for the future?* Meat Science, Volume 120. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/27211873>.



NCBA is aware of anti-animal agriculture activist assertions that due to the absence of slaughter and differences in production method FSIS lacks both the authority and competency to regulate cell-cultured meat products. Not only are these assertions willfully ignorant of the law, they grossly underestimate FSIS's significant scientific expertise and food safety accomplishments. For example, approximately 67 percent of the facilities inspected by FSIS are "processing only" facilities, which adhere to stringent sanitary design principles to ensure in many cases a sterile environment.

It also is imperative that the regulation of cell-cultured products derived from livestock and poultry begin with a fundamental component of inspection under FMIA – that every animal is subject to ante-mortem inspection. While the proposed joint oversight framework places "cell collection" within FDA's purview, cells should not be taken from any animal whose health has not been verified by an FSIS inspector. As such, the agencies should consider the importance of FSIS's role throughout all stages of the cell-culture production process, including pre-harvest. The FSIS mark of inspection is a powerful regulatory tool, and no product should receive the benefits provided by this mark unless subject to the full extent of regulation under FMIA.

Cell-cultured meat labels should be held to the same exacting standards as beef.

Beef producers have always been happy to compete on a fair, even playing field. However, that level playing field is as much about nomenclature as it is about safety assurance systems.

As cell-cultured protein products come to market, they must be held to the same nomenclature standards as other products under FSIS oversight. FSIS has strict rules regarding the content and appearance of meat and poultry product labels. These rules include everything from dating and safe handling instructions to font size. These strict labeling requirements protect consumers by providing them with the knowledge needed to make informed purchasing decisions.

FSIS's mandatory labeling pre-approval process ensures that each product label accurately depicts the product in the package. FSIS has established and approved definitions for many types of meat and poultry products. Traditionally, if a definition or "a standard of identity" does not exist, a common or usual name may be used. If neither a standard of identity nor a common name exists for the product, a descriptive name must be used.

Some within the cell-cultured industry have already begun to engage in misleading marketing efforts that unfounded claims about their products and disparage beef. The clearly stated goal of these efforts is to enhance consumer acceptance of cell-cultured meat products, not promote a label that is scientifically accurate.⁵ In light of this behavior, NCBA encourages FSIS to:

- Consider developing a federal standard of identity cell-cultured products that clearly differentiates them from beef;
- Develop appropriate labeling descriptors that will promote honesty and fair dealing for consumers;

⁵ Good Food Institute. *Clean Meat: The Naming of Tissue-Engineered Meat*. Accessed on December 20, 2018. Retrieved from <https://www.gfi.org/the-naming-of-clean-meat>.



- Ensure that a government entity is responsible for verifying, on a scientific basis, the contents of the product label and any associated marketing claims (*e.g.*, “sustainable”); and
- Conduct a comprehensive consumer survey to evaluate consumer perceptions of cell-cultured protein products and labeling descriptors, with the goal of developing a label that gives consumers enough information to make an informed choice.

The recommended objective, government-sponsored survey is particularly important in developing appropriate nomenclature for cell-cultured products. Surveys conducted by groups with their own, vested commercial interest must always be viewed as biased. By contrast, a government survey can aid in the development of new, unique nomenclature that is reasonable, scientific, and based on detailed research about what will most benefit consumers.

Cell-cultured meat manufactures should not be permitted to use the term “beef.”

In conclusion, NCBA firmly believes that the term “beef” should only be applicable to products derived from livestock raised by farmers and ranchers. Producers in the beef industry have worked hard to build our brand and differentiate our products. Consumers have come to expect satisfaction and a high-quality eating experience from beef. Manufacturers of cell-cultured products must find a way to differentiate their products in a way that clearly identifies the production process and does not infringe on beef’s hard-earned and well-deserved reputation.

Our industry welcomes innovation and consumer choice, but competition must take place on an even playing field. Cattle producers and the rural communities that depend on them cannot accept federal government action that advantages one food product over another. For this reason, we continue to believe FSIS’s primary oversight role is imperative for both consumers and producers.

Thank you for the opportunity to submit these comments. Should you have questions or seek additional information, please contact Danielle Beck, NCBA Director of Government Affairs, by phone or email (202-879-9127 or dbeck@beef.org).

Respectfully,



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