

## USDA-FDA Joint Public Meeting Day 2 Afternoon Session

Selena Kremer,  
USDA FSIS Moderator

Welcome back from lunch everyone. I hope you enjoyed your lunch. We're going to go ahead and get started with our next session. Next, we have an open public comment period on potential claims. Jeff Canavan and Douglas Valentine just gave their presentations right before lunch on labeling claims, and now will be your opportunity to make additional public comments. As you've seen throughout yesterday and this morning, there have been quite a few opportunities for you to provide public comment. We've got just a couple of those sessions remaining today, so we're getting to the end of your opportunities to come forward and speak and tell us your views. We'd really like to hear from you. This is your opportunity. If we can have our ushers come forward. If anyone would like to come forward. We're talking about what factors should be considered in potentially allowing health safety and other claims in the marketing of animal cell culture products. If anyone would like to come forward and make comments, please come forward. Go right ahead.

Patty Lovera,  
Food and Water Watch

Hi my name is Patty Lovera. I'm with Food and Water Watch. My colleague Amanda Starbuck gave a formal comment yesterday, so this is just additional. Based on this morning's discussion about claims and label context, I think the context is super important for folks who are talking to consumers, because consumer advocates, lots of folks who are raising all of these types of questions that you've heard, we're like this for a reason. We're like this for a lot of reasons, and those reasons are previous battles over what you can say on food labels and the confusion and kind of general chaos that people are experiencing. Right now in the food marketplace, what we do know, what is clear is that consumers are incredibly interested in the methods and the process and how their food was produced and that's very clear I think in the growth of things like the organic label, which as I am reminded constantly by AMS, is a process-based label and not an outcome-based label and that label is growing by leaps and bounds in the marketplace, because it tells people something about the methods used to produce their food, and people are responding to that. We're having a conversation right now in this building about what the GMO label is going to be, and there's a lot of debate about how much information it's going to give people about the process, what methods are included, and the resounding information that we've gotten from our members and supporters is that they want to know as much as possible about those methods. Then there's lots of other controversies in the food labeling world that speak to consumers. We need more data. We need to understand better, but it speaks to their kind of reaction when they feel like they didn't get all the information about what a short label says and at the risk of

inflaming an old controversy. I think the controversy about whether you call it pink slime or whether you call it lean finely textured beef, people reacted really strongly to that being included under the simple label of beef when they felt like that product was something different, and I think we need to look to that as we figure out what to call these technologies we're talking about today. The history of how we've gotten to this point with a lot of food standards is about expectations. I'm wanting to know about the process, but it's also about previous bad experiences with what people perceive as fraud, and that has to be part of this conversation. To get to the second piece of it, of sustainability claims, I think there's currently a lot of confusion about how we talk about sustainability and how food is produced; I think we need to include other agencies that know how to think about that. The EPA and life cycle assessments, the Federal Trade Commission as they look at other green claims, but I think the most important thing that we would want to inject into that conversation is that we have to count all of the inputs. So it's water use. It's what materials you need to make these products grow. It's antibiotics, growth factors, and hormones, but also what else they take. If we're talking about some of the parallel technologies of genetically engineering a yeast to produce something that you turn into a meat substitute, what is that yeast going to eat? What is that feedstock? What is the footprint of that feedstock? That has to be part of the calculation we make when we tell consumers something's sustainable. We need rules to do that because, right now, right now without these products, we have a lot of confusion and adding new technologies could lead to even more. I'll stop there. Thanks.

Selena Kremer,  
USDA FSIS Moderator

Thank you so much.

Melissa Ahlborn,  
The Good Food Institute

Hello. I'm Melissa Ahlborn, senior regulatory specialist at The Good Food Institute, and we would like to clear up a misconception that came up yesterday related to the safety of cultured meat, although this could bear on the discussion today as well. This comment that I'm about to give is based on consultation with GFI's science and technology experts. Following yesterday's sessions, some commenters referenced a literature review article written by a small group of social scientists, chemical engineer, a biomaterial scientist, and some farmers in the UK that called for more research to quote, confirm, or dispel uncertainties over the safety of ingesting genetically modified cell lines as these lines exhibit the characteristics of a cancerous cell, which include overgrowth of cells not attributed to the original characteristics of the population of cultured primary cells, end quote, and the references. Stevens et al. The authors seem to be referring to the use of immortalized cell lines created through genetic engineering, and genetic engineering is not required for cell immortalization. If immortalization of cell lines is a goal,

some proliferative cells can be immortalized without genetic engineering. Their so-called footprint free methods that do not introduce foreign DNA into the cells but do reprogram the cells to a pluripotent state, so they're capable of multiple rounds of division and differentiation into multiple tissue types. To our knowledge, cultured-meat companies are not currently ~~using~~ using genetic engineering to alter cells, but, if genetically engineered cells were used by a company at some point in the future, the genetically engineered cultured meat cell lines could be regulated by the FDA under existing guidelines. Related to this issue, there's also a couple of important points to understand. Ingesting cancerous cells is not a safety issue as, one - the cells are not viable when eaten, two - your body digests and destroys the cells; and three, conventional ~~animal~~ animal meat products can already contain cancer cells. Of course, FSIS does not allow cancerous lesions or tumors to enter commerce or the food chain, but it is impossible to keep all cancerous cells from reaching consumers in conventional meat. It was suggested yesterday that regulators should request data on whether lab meat will contain oncogenes that are expressed, and, if so, make a determination as to the appropriateness of consumption. To be clear, there's a significant difference between a cell expressing oncogenes and a cancerous lesion or tumor. An oncogene has the potential to create a tumor, but the presence of one does not indicate a cancerous lesion or tumor. Furthermore, oncogene expression can be tested for during the manufacturing process. In fact, one advantage of cultured meat is that one can sample the cells in each bioreactor and get an indication of potential hazards. It is impossible, however, to sample every animal or even every tissue in an animal that will become meat for consumption. For example if it was determining that there was a threshold level of expression for a certain oncogenes, this could be easily tested for during cultured meat manufacturing but not as easily tested during the breeding and slaughter of animals.

Selena Kremer,  
USDA FSIS Moderator

Thank you.

JanLee Rowlett,  
Iowa Cattlemen's Association

Thank you. Good afternoon. My name is JanLee Rowlett, and I am here on behalf of the Iowa Cattlemen's Association. I was not registered to provide formal comments, but I would like to offer these thoughts informally. And also thank USDA and FDA for hosting this meeting and providing an opportunity to provide comment. Cattle producers across the country take great care and great pride in providing beef for tables around the world and depend on fair and accurate labeling to market our product. Fair and accurate labels on beef and all food products are crucial to maintaining confidence by purchasers that they are getting what they are paying for. In a world of where consumers are as far removed from food production as at any time, and labels are more important now than ever. While there are still many unanswered

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questions surrounding cell culture technology, when it comes to labeling, there are two principles we stand behind. First, fair and accurate labeling of meat food products no matter how they are produced means the same labeling standards across the board. Second, fair and accurate labeling; it means using beef and other terms consumers associate with meat products made from livestock that are raised by farmers and ranchers describe only those products, not those produced through cell culture technology. These objectives can be achieved only under the primary jurisdiction of USDA's FSIS, which will ensure a sound scientific basis of labeling and approval of these products before products are offered on the market. We believe the pre-approval of these labels is absolutely critical to preserving the integrity of all meat offered for sale to American families. Thank you.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. Our next commenter.

Liz Holtz,  
Animal Legal Defense Fund

Hi. My name is Liz Holtz, and this will be my formal comment. Again, I'm speaking on behalf of the Animal Legal Defense Fund. On the question of labeling, it's clear that consumers care about the way their food is produced, and specifically about the way animals are raised and treated to make animal products. Consumers increasingly seek out meat and other animal products produced without certain attributes that they view negatively, such as raised without antibiotics, cage free, or no hormones. We've heard many comments about the need for labeling transparency and to provide disclosures as to the production method of cell-based meat products. We've long called on USDA and FDA to prevent consumer deception caused by inconsistently defined and inadequately policed labeling claims on meat, poultry, and egg labels. By requiring uniform labeling disclosures of certain animal production practices, like whether animals have been administered antibiotics and whether eggs are sourced from hens raised in cages. Today, both USDA and FDA have refused to do so, viewing production methods as matters of voluntary labeling claims only. It would be patently unfair and inconsistent then to require such disclosure of production methods only for animal products made through cellular agriculture, but not for slaughter derived products, particularly if cell-based products ultimately present fewer food safety and public health risks than do slaughter-based products. Indeed, several commenters have implied that consumers are familiar with how conventional meat is produced on today's farms and that this requires cell-based meats to disclose their production methodology because it's something different than what we expect. This is false. The average consumer does not purchase conventional meat products knowing that the source animals were bred to maximize production at the expense of welfare; the drugs are received routinely used to enhance growth; or that animals are kept in crates and cages so small that they can't turn around. Consumers care

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about animal welfare yet remain in the dark about these practices. A level playing field thus requires labeling transparency across the board, not just for cell-based products. We're at a crossroads in animal agriculture that raises greater questions of how best to ensure food safety and prevent misleading labeling. Whether we're talking about cell-based or slaughter-based products regulation should not hamper the great potential that cell cultured products hold for our food system, consumers, and farmed animals. The potential to serve the protein needs of a growing global population in a manner that doesn't rely on the suffering of billions of animals every year does not ~~stick, and~~ sicken consumers with drug-resistant pathogens, does not pollute our air and waterways, and does not foster antibiotic resistance that threatens public health. The stakes can be higher for this new technology. Thank you for taking it so seriously.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. We have anyone else that would like to come down and participate in this open comment period?

Barbara Walsh,  
The Ohio State University

This is Barbara Walsh at the Ohio State University, and this will be my last comment. All this isn't formal, still informal. One thing that has really struck me over the past three days as I've listened to this, is that this is really an exciting new area, and there is a lot of innovation people are excited about, that is getting a lot of attention, but there are a couple things that have really struck me. One thing that I've heard a lot is 'we expect...' And as a scientist, that kind of bothers me and leaves me wanting. I think we were to go beyond expectations to actually prove the risks and benefits of this new technology on these new food products. There's been a lot of people across the stakeholder groups talk about risk-based. If you know me, I've advocated for risk-based food safety systems, I think now, most of my career. It strikes me that again that maybe not a lot of people know or who understand what risk-based means. I had the honor of serving on a National Academy of Science committee several years ago that defined what a risk-based food safety system was, or is. It one that is proactive, anticipatory, science-based and data-driven. And, I think if you apply those standards to this situation, we will need more evidence before we can say what are the risks and what are the benefits to this new product. Now our approach to drugs have largely been with this paradigm. It is to be on the drug side of things. I'm used to working with pharmaceutical research, and we did a lot of information. We do a lot of research and experimental studies to ensure the safety of products before they're put out in the marketplace. It is proactive and anticipatory. In food, however, we tend to put things out, and then worry about the what happens afterwards. And, it's been criticized that our food system is reactive, and I agree with that statement. What I'm worried about here is that the excitement about the potential benefits of this new

technology is maybe clouding our judgment around what are the unintended consequences, and there's almost always an unintended consequence when we disrupt a system in this way. And so, I would encourage the agencies and the producers to think about the potential unintended consequences of changing this system. The final thing that I wanted to comment on is that we need a lot of research into this area. I will say food safety research is grossly underfunded currently, and that means that we're going to need to advocate for more money to be put in this area. I'm also very concerned, and nobody's has talked about the resources of FDA and USDA, that they currently have to handle the mandate that they already have ongoing. We were implementing a major new law, FISMA, at FDA that's been going on for years. They don't have all the resources they need, not just financial resources, but also scientific resources. I've heard too many times about how the agencies are having challenges recruiting in good scientists to address all the regulatory needs that they have. And USDA's under a similar situation. We're going to add another very complex process to this system. I just think that we need to, as a community, be thinking about the resources needed to fully and effectively implement it. Thank you.

Selena Kremer,  
USDA FSIS Moderator

Thank you. Our next commenter. Yes.

Michael Hanson,  
Consumers Union

My name's Michael Hanson. I'm a senior scientist at Consumers Union. That's the advocacy arm of Consumer Reports. And, in terms of safety or benefit claims for this, I think I would just like to talk about two particular issues. One is a use of antibiotics and that is of crucial importance for human health and even in the marketplace. As FSIS has noted, most of them, they're seeing an uptick in in claims for what they call negative; that is, no added hormones, no antibiotics, or raised without antibiotics. And, we already see from various consumer campaigns, most of the fast-food chains -- for example in the chicken area -- they are now only serving chicken that is raised without medically important antibiotics. In fact, about 50% of all chicken production in the U.S. is raised without any antibiotics. The question is, and we don't have the data, it's my understanding after these cell culture systems, these animal cell culture systems, you have to use antibiotics, so you cannot make the claim that it's produced without antibiotics. And, it would be nice to see how much antibiotics are being used to produce a kilogram or a pound or per unit quantity of any of these meats, so we can start to compare that data, because, in Europe, we have good data to know how much is being used per quantity of meat. We're starting to do this in the U.S., and I think that's actually crucial in the area of the use of hormones, all these various growth factors, they are hormones. Those are added hormones to the system, and I don't know if consumers realize that; I would ask the companies, if you're being transparent, be open about the fact that you're using

antibiotics and you're using hormones in these are in these production systems. If you can achieve a production without that, please come to us with some of that information so that we can when we talk to consumers about these products, we can mention whether they have added hormones in them or whether they're are antibiotics being used in the production process, because I don't know presently of any cell culture system that doesn't use antibiotics and other anti-microbials in the growth medium. And this is not just against antibiotics; it's not just against bacteria. You have to add things to not only kill fungi but chemicals to kill mycoplasma. Those aren't necessarily being used in conventional systems; we really need to have data on how much antibiotics, how much these hormones are being used in these products, so that we can start to compare them with conventionally raised products to see how much better they are, if they are in indeed better. Thank you.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. I think we've heard a lot of great diverse opinions here today. And if you still haven't come forward and made a comment and would like to do so, now is a great opportunity to do that. We're going to move shortly into our formal comment period. This is the right at the end of our open comment period. Please don't miss your opportunity. Seeing no takers, we're going to move on to our formal comment period. We have a number of folks that have pre-registered to speak today, and some of them have already come forward yesterday and earlier this morning to make comment, but we still do have a few folks that have registered, and we'd really like to hear from you. Let's start with Group 2A. If you could please state your name and affiliation.

Eric Sumption,  
South Dakota Stock Growers

Eric Sumption with South Dakota Stock Growers. I do not support foods processed using animal cell culture technology as being labeled meat, and related products not be labeled as beef, poultry, and seafood. As a fourth-generation farmer and rancher from South Dakota, I know all about the investment and the time and it takes to produce these animals. My family and I care for each animal every day from the moment they're born until they're delivered to the harvest facility. Throughout their life, we ensure they are healthy and have access to nutritious high-quality feed. The term beef is our brand applied to the product and livestock producers like me, my father, grandfather, and great-grandfather worked generations to perfect. At the same time, we've worked for generations to develop trust among consumers, trust that when they eat beef it's raised by American ranching families, they are consuming a product that is safe, nutritious, and tasty. Inaccurate and mislabeling jeopardizes the trust that we've built with consumers. Food products using animal cell culture technology are derived from animal cells grown in a petri dish or other ways. Consumers do not trust

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these foods to the same extent that the food they trust is derived from animals raised by U.S. farms and ranches. Cell cultured proteins should not be allowed to be drawn upon as U.S. livestock producers reputations and producing safe nutritious and high-quality meat. Common names, such as meat and beef, are widely understood by consumers to be the tissue and flesh of animals that have been raised and harvested in a traditional manner. Food labeling should reflect that understanding and protect consumer trust harvested in a traditional manner. Similarly defined as beef, chicken, or pork and other related products should be restricted to tissue of cattle, chicken, hogs raised in traditional manner. Both FDA and FSIS have a responsibility to ensure that food labels are not false or misleading. The Federal Meat Inspection Act and the Federal Food Drug and Cosmetic Act requires FSIS and FDA to respectively prohibit misleading labeling, including for imitation products. All consumers have the right to know what they are purchasing. This new cell culture technology, and industry should not be allowed to take advantage of the reputation of family farmers and ranchers have worked so hard to build. The truth is in the labeling. The public deserves the right to know where their food comes from, originates, whether it's in the U.S. or another country. Please do not allow for food produce using animal cell culture technology be labeled as meat. Furthermore, do not allow related products to be labeled as beef, chicken, and pork or any other name that is widely recognized consumers as deriving from an animal born, raised and harvested in a traditional manner. I would like to thank USDA and FDA for allowing me to make comment today.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. And, anyone else from Group 2A or Group 2B that would like to come forward? Thank you.

Brian Spears,  
New Age Meats

Hello again. Brian Spears, co-founder and CEO of New Age Meats. We make meat from animal cells, not animal slaughter. We make pork. And, first off, it's good to be home. I grew up around here in Northwest Maryland little town of Boonesboro, population 2,500. Anybody know it, Boonesboro? All right, few of you. The reason I was here is because my father was career FDA. My whole life growing up, I heard I heard stories about the FDA's work that that they did or that you do balancing innovation to help people become healthier with safety concerns. And, actually most of my life growing up I defended the FDA and still do to friends who thought that they were too slow bringing drugs to market to help people through him in his network I gained an appreciation for also the USDA and the fantastic work that the USDA does in keeping us safe. To both institutions, I say thank you. We support both FDA and USDA's involvement in the regulation. Cell-based meat, FDA's extensive work developing regulatory frameworks for cells and products like biologics, makes FDA the obvious choice to be the leading partner based

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on their long-standing history of public health protection. FDA will also be effective in protecting the public from entities that may cause counterfeit or that may create counterfeit and potentially dangerous meat. The cell-based meat industry will create innovation that will make America a world leader in the next generation of safe healthy food but it's more than that. I was pulled aside recently by a researcher on culturing heart muscles for human patients. He said, do you realize that if you meet your goals regarding cell growth, that you will solve some of the biggest issues that we're struggling with? I'm so excited for your field. This is what he told me, where do we want that innovation to occur? Companies around the world are working on this technology. We have been contacted by representatives from the governments of China, Singapore, India, and others. They say, can you please set up your company in our country? We'll ensure a clear regulatory pathway. I say, no, I'm an American. I want to do this here. My question is, will you let the existing meat processing jobs that are among the most dangerous in the country or will you let us create safe high-paying American jobs both in R&D and manufacturing from the coast to the heartlands. I'm really encouraged that the USDA and FDA are working together to create common-sense guidelines that calls meat "meat" and guidelines that recognize that our production methods make Americans safer, healthier, and more prosperous. Thank you very much.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. Do we have anyone else from group 2A or 2B?

Peter Licari,  
Just, Inc.

My name is Peter Licari. I represent Just, and we are focused on commercializing cultured meat. Although difficult to do in three minutes, I would like to demystify the first type of meat we will produce and sell using animal cell culture technology. The meat looks like chicken when it is uncooked. The meat looks like chicken when it is cut. From an analytical perspective, it is comparable to conventional chicken. In our test kitchen, we have served people chicken produced using this approach, including top executives from large global meat companies and award-winning chefs. The reaction of people tasting our chicken is uniformly, "Wow, this is chicken." Behind this chicken is a set of techniques routinely employed for decades to produce biopharmaceuticals. And, to address the earlier comments, we do not use antibiotics. We believe there are three pillars. Critical and appropriate sound regulatory oversight. First, the starting cell bank, the master cell bank, is well characterized and free of adventitious agents. Second, the production process is consistent and well controlled. And, third, the final product is well characterized and comparable to conventionally produced meat. Although our culturing process requires sterility from environmental contaminants, we feel regulatory oversight consistent with other food products is sufficient to assure safety and

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public health. Our meat products are intended to be comparable to conventionally produced meat as opposed to novel substances without a history of safe consumption. The long history of safe consumption of conventionally produced meat means that the cultured equivalents are also safe, if demonstrated to be produced under these three pillars. With regard to the labeling of cultured meat products, we feel that there should be both a regulatory nomenclature that is a statement of identity and consumer-facing nomenclature that sufficiently differentiates cell cultured products from traditional meat products, but appropriately acknowledges that these products are meat. We propose that labels for cultured meat products include the following elements: first, on the front and center of the label the name of the brand, as an example, Sunshine Meat Company; and, two, below the brand name, a statement of identity which indicates that the product is cultured as well as the species from which the product is derived, for example, cultured chicken breast. We believe this format satisfies regulatory and consumer interests while fitting into previously approved formats. Thank you for your time.

Selena Kremer,  
USDA FSIS Moderator

Thank you.

Kevin Kayser,  
National Cattlemen's  
Beef Association

Good afternoon. My name is Kevin Kayser. I'm a fifth-generation rancher from Parkville, California, and president of the National Cattlemen's Beef Association. On behalf of NCBA, thank you for the opportunity to comment on an issue of great importance to consumers and beef producers across the United States. Product labels are a defining feature of the shopping experience for consumers, whether the product is food or another consumer good or, if the venue is in person or online. Labels are designed to communicate specific product characteristics and attributes. Manufacturers, advertisers, and retailers all understand the value a label can deliver. The Federal Government understands this too. That is why our legal system requires fair and accurate product labels. Manufacturers, advertisers, and retailers all understand the value of a label. It makes clear that words and claims matter. In this spirit, two critical steps must be taken to ensure that lab-grown, fake-meat labels are fair and accurate. First lab-grown, fake-meat labels should be held to the same standards as other meat labels given that the goal of these products is to compete directly with the real meat. Only USDA oversight can adequately ensure this outcome. Some proponents of the lab-to-fork industry have already begun to engage in misleading marketing efforts that promote unfounded claims about lab-based products and disparage real beef. These advocates are unapologetic about their desire to enhance consumer acceptance of lab-grown fake meat products. They are not concerned with an accuracy

of terms such as “clean meat,” which have no scientific basis. USDA can be trusted to enforce truthful and transparent labeling of the products under its jurisdiction. USDA requires that all product labels be based on sound science. It also requires all labels be approved by the agency before hitting store shelves. This pre-approval process gives USDA the opportunity to stop false and deceptive marketing claims before product labels enter the marketplace. By contrast, the Food and Drug Administration does not require pre-approval of product labels. Manufacturers are free to label their products as they see fit, and some worry about potential consequences later. And, unfortunately, the FDA has consistently shown that it is either unwilling or unable to enforce product labeling standards. That agency turned a blind eye to labeling abuses from fake milk manufacturers for nearly three decades. Second, lab-grown fake meat manufacturers must not be permitted to use the term beef, and in the associated nomenclature. The 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 real beef. The manufacturers of lab-grown products should be required to invest in their own market development efforts and not ride the coat tails of beef’s success. As lab-grown fake meat products seek to differentiate themselves to consumers, NCBA encourages the USDA to consider developing a federal standard of identity for these products, as well as appropriate labeling descriptors, as that is the best way to promote honesty in fair dealings, in the interest of consumers. If after scientific review it is determined that lab-grown fake meat products meet one of the definitions and laid forth into the Federal Meat Inspection Act, there is no legal justification that would warrant FDA's involvement in inspecting these products, including their labeling or marketing. Thank you again for the opportunity to provide comments. The NCBA looks forward to engaging with both agencies in this process moving forward.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. Our next commenter.

Mike Selden,  
Finless Foods

Mike Selden, co-founder and CEO of Finless Foods. Just quickly. I do believe it is important that we are allowed to use the correct terms when marketing our products, which for cell-based beef would include the word beef. For cell-based salmon, would include the word salmon. And this is very important. I'd like to read something. Anaphylaxis is a severe potentially life-threatening allergic reaction. It can occur within seconds or minutes of exposure to something you're allergic to. Anaphylaxis causes your immune system to release a flood of chemicals that can cause you to go into shock. Your blood pressure drops suddenly, and your airways narrow, blocking breathing. Signs and

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symptoms include a rapid weak pulse a skin rash and nausea and vomiting. We've got some stats. 33 percent of anaphylaxis cases were from alpha-gal, which is something found in meat specifically. If people don't understand what we're making, it will cause them this life-threatening allergic reaction. We are creating a public health hazard. It is extremely important that we use these words. And also, to respond to something those brought up earlier. In terms of our process, we do not use antibiotics. No large-scale cell culture system uses antibiotics. Best practice for large scale cell culture system does not use antibiotics. I don't know a lot about the other companies in this field, but for fish, antibiotics kill our cell culture pretty much every single time, so it's not something that we actually can use at any point in the production process. Thank you.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. Our next commenter.

Justin Oldfield,  
California Cattlemen's  
Association

Good afternoon. Justin Oldfield on behalf of the California Cattlemen's Association in Sacramento. Again, when I think the comments raised by colleagues in the livestock industry and want to associate our comments today, principally of those made by the National Cattlemen's Beef Association. We fully recognize that debate will continue as to what these products should be called moving forward, and although we have not firmly determined what the nomenclature should be, our producers will seek a labeling regime that provides a clear separation between lab produced products and conventionally grown meat. And if we can reiterate the fact beef is from, meat derived from cattle produced by farmers and ranchers period. We went back to the conversation that occurred yesterday and the need to better define the roles and responsibilities and jurisdictions of USDA and FDA on this issue. It does highlight the need for FSIS to assert primary jurisdiction, not only on the safe production of lab-grown products, but also on labeling. FSIS oversight will ensure labels are accurate, devoid of disparaging claims, and based on science, not deceptive marketing schemes. We must prevent false or inaccurate statements made not just on what was produced but how it was produced. FSIS can do that, which is why we must ensure their involvement from the lab or production facility to the store shelf. I don't believe the concerns raised by livestock producers are misguided or unreasonable. We have already heard lab grown products referred to do in the public realm as being clean or antibiotic free. We know these statements are completely subjective and, in some cases, to be untrue. As discussions and collaborations between both agencies move forward, we urge FSIS to seek and assert primary jurisdiction over the safe production and labeling the lab-grown or cell culture products. Thank you.

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Selena Kremer,  
USDA FSIS Moderator

Thank you. Do we have anyone else from a group? Please come forward if you'd like to make your formal public comment now.

Nigel Barrella,  
Attorney

Hi. Nigel Barrella, a private attorney speaking for myself. On the labeling issue, we have heard a number of speakers talk about how these products shouldn't be labeled as meat or beef, and I would like to draw a distinction between labeling something as "something," labeling it as meat or a label referencing a meat product so with an appropriate qualifier like cell-based or cultured or something that no one has thought of yet it's. It's not misleading to a consumer to reference another product, and frankly, this isn't the first time this issue has come up. In the 1980s and 70s, even FDA was addressing complaints from dairy producers that low-fat cheeses shouldn't be allowed to reference the word cheese. They should make up some fanciful term to describe this this weird new product. USDA itself in the 80s got sued for allowing products to call themselves "turkey ham," which is kind of a salted turkey product that is kind of like a ham. The pork producers sued over that saying, no you can't you can't call this ham. Ham is pork. Only yesterday we heard tofurkey sausage apparently or plant-based sausage has drawn some ire. Obviously over at FDA there's the soy milk/soy yogurt/soy cheese issue. Those are pretty clear terms that both agencies USDA and FDA have themselves used, but the dairy interests are saying, "Police this language." Don't let non-dairy products even reference dairy terms. More recently, rice producers have complained about this trend of rice to vegetables, which are like cauliflower minced up really small to look like rice. We could go down this rabbit hole of having these agencies try to police language, try to police new products, but it's not a good use of agency resources. There's nothing here about misleading or deceiving consumers as long as the products are appropriately explained. The nature of these products is clear, and if the agencies did go down this road of trying to police language, there is a First Amendment issue here. Producers have a First Amendment right to use terms that explain their products to consumers in the most natural understandable terms and forcing unnatural names like cell cultured cell-based food from chickens or whatever was proposed yesterday, or anything like that, would run afoul of that. And in closing, I'd also note that as a lawyer I'm not persuaded that USDA actually has authority to regulate cell culture products. I understand kind of the political compromise at work here, and it's only really a problem if someone finds cause to challenge it. And I think that if USDA kind of went too heavy-handed on the labeling or other issues of these new products, that could give someone cause to challenge USDA's Authority in this area. That concludes my time and my comment. Thank you.

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Selena Kremer,  
USDA FSIS Moderator

Thank you. Our next commenter.

Karla Hofhenke,  
South Dakota Farmers Union

Good afternoon. My name is Karla Hofhenke. I am a fourth-generation cattle producer and the Executive Director of South Dakota Farmers Union. I oppose allowing foods produced using animal cell culture technology to be labeled as meat and related products to be labeled as beef, poultry, and seafood. South Dakota Farmers Union has long advocated for transparent and truthful labeling of meat products. Much of our concern has revolved around ensuring that consumers know what country their meat comes from. That work, whether it be focused on country of origin labeling or product of USA standards, has been driven by a basic principle. Consumers want to know what they are purchasing, and our livestock producers are proud of the product they produce. And, we want to tell them, with the development of animal cell culture technology, another layer of uncertainty is being added to consumer awareness and choice when purchasing their favorite meat product at the grocery store. A consumer has the right to know where their animal was raised. They should also know that the product does, in fact, derive from an animal that was raised and harvested in a traditional manner. Allowing a protein that is grown in a petri dish to be labeled as meat is misleading, and it creates consumer confusion. The only sure way of avoiding misleading consumers is to restrict the definition of meat to the tissue or flesh of an animal that has been born, raised, and harvested in a traditional manner. Likewise, the definition of beef should be restricted to products deriving from cattle born, raised, and harvested in the traditional manner. That definition standard should be applied across all meat products by FSIS, FDA, and any other relevant federal agencies. In a recent Consumers Report survey, less than one-third of consumers said they would be willing to eat *in vitro* meat as a replacement for farming. Allowing ambiguous labeling of cell cultural proteins and traditional meat products will confuse consumers, making it difficult for them to exercise their preference. Farmers Union shares many of the safety and health concerns that have been discussed over the last few days. FDA and FSIS each have a responsibility to protect the safety of our nation's food supply. And I'm encouraged by the two agencies' collaboration on this issue and optimistic that the regulatory framework around cell cultured proteins will be consistent with all food products. Consumers have the right, and they are demanding to know what they are purchasing and eating. The truth should be in the labeling. Please do not allow foods produced using animal cell culture technology to be labeled as meat and the related products to be labeled as beef, poultry, and seafood. Thank you for consideration of this testimony.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. Do we have any other commenters from

Group 2C or Group 2D?

Rebecca Cross,  
Outermost House

Hi. My name is Rebecca Cross. I'm here representing Outermost House, which is an incubator and innovation center for food companies that are making replacements for conventional animal products. We are based in the San Francisco Bay Area in California and are in the process of building out a research and development and pilot production facility to support these companies, where we will provide business services as well. I have also been a food regulatory attorney for over a decade, most recently with the international corporate law firm, Davis Wright Tremaine. My specific area of expertise is food labeling. That is what I'm here to comment on today. As most of you know this segment of the food industry making replacements for conventional animal products is rapidly growing based on high consumer demand. Consumers of these products want transparency. They do not buy alternative products because they confuse them with their conventional counterparts. They buy them because they are alternatives. That is what is driving sales here. Likewise, companies making these products want transparency as well in order to appropriately describe their products. Companies making replacements for animal products must be able to use the names of what they are replacing so that consumers have a basis for comparison and can identify products with common language, whether it be plant-based milks, cheeses, or meats. For the products we are discussing today, plant-based products like the two packages of sausages that were introduced yesterday, differentiate themselves from their conventional counterparts by describing themselves as plant-based, veggie made from wheat gluten, made from soy, etc. Cell-based meat, on the other hand, will be made from real animal cells, just with a different production process. As such, they should be allowed to call themselves simply beef, chicken, pork, tuna, etc., without being required to disclose their production methods or otherwise differentiate themselves, just as synthetic ingredients that are currently on the market today are not required to disclose their production methods. For example, synthetic citric acid is appropriately labeled today as citric acid, and, as Mike Selden from Finless Foods discussed, cell-based meat is not synthetic, it is made from real animal cells. I can think of no example where a food product or ingredient originating in a lab is required to label itself differently than its conventional counterpart. And I believe that under either the FDA's or the USDA's labeling regimes, these products should be able to label themselves in the same way as their conventional counterparts. That being said, we understand that companies in this space want to differentiate themselves and to affirmatively disclose their production methods. To that extent, companies should have the option to do so. And as Dr. Schulze from Memphis Meats has explained, the term cell-based meat is clear, factual, and inclusive. Other descriptions like cultured or slaughter-free would be accurate as well. Several commentators have

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expressed their concern here that new products not be labeled in a way that will disparage conventional animal protein. I understand this concern; however, I urge the FDA and USDA not to use this rationale to prevent cell-based meat products from accurately describing themselves as slaughter free or assuming sufficient factual basis having reduced environmental impacts or reduced risk of bacterial contamination. Thanks very much. Thank you.

Alain Rostain,  
Simple Foods Collaborative

Hi everybody. How you doing? I just want to point out that the term cultured meat will actually not work. I assume you want the same term for being efficient.

Selena Kremer,  
USDA FSIS Moderator

Oh, pardon me. Please state your name and affiliation.

Alain Rostain,  
Simple Foods Collaborative

I'm sorry. Thank you. Sorry. I'm Alain Rostain from Simple Foods Collaborative, a cell-based seafood company. I just want to point out that the term cultured will not work. I soon want the same term for beef, chicken, and fish. Cultured fish means fish raised on farms, and when our first products get to market, they'll have to be labeled something that doesn't mean fish raised on farm. I just want to point that out for the record. Thank you.

Selena Kremer,  
USDA FSIS Moderator

Thank you so much. Anyone else that would like to make formal comment today?

Brett Kenzy,  
Cattle Producer  
Self

Hello. I'm Brett Kenzy, and I'm making formal comment on behalf of myself as an individual. I do not support foods produced using animal cell culture technology being labeled as meat. I further believe that related products should not be labeled as beef, poultry, or seafood. I'm a fourth-generation cattle producer from South Dakota. My brother and I operate and manage a South Dakota DNR permitted feedlot and maintain a commercial cow herd. Our goal is to raise and care for cattle that produce the finest quality beef for our consumers and to become proper custodians of the environment. In that pursuit, cattle produce a hundred percent of our income. We intend to create opportunities for our children to continue this ranch. I did not leave our ranch at the busiest time of an always busy year to take a stand against the existence of cell culture technology. Rather, I'm here to advocate for truthfulness and transparency in regard to the labeling of our food. USDA and FSIS are funded by American tax paying consumers. These agencies,

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comprised of bright, well-meaning people, oversee the safest, most humane and environmentally safe beef production system in the world. Unfortunately, the USDA and FSIS' inability to operate independent of political influences has allowed financial and trade pressures to compromise truthfulness and labeling. At times, the fact that meat from 18 countries can be shipped into this country and labeled as U.S.A. product proves that our system does not always have the American cattlemen and consumers best interest at heart. The previous statement may sound coarse. I don't mean to be inflammatory but, and I capitalized this, CONSUMER CONFIDENCE MUST TRANSCEND POLITICS. This absolutely applies to how we will choose to label cell culture products we need to get this right. Finally, I've learned that at least two of the four global meat processors that harvest eight and a half out of every ten cattle in this country have invested heavily in cell culture technology. This alarms me as my biggest fear is not competing with clearly labeled stand-alone cell culture products; my fear is of a product that blends cell culture product with natural meat. This would add another invisible competitor to the natural beef supply and demand matrix. Ambiguous labels that create an illusion of choice are my primary concern. The truth should be in that labeling integrity matters, and competition makes us all try harder. Thank you for your consideration of this testimony.

Selena Kremer,  
USDA FSIS Moderator

Thank you so much. Anyone else that would like to comment? If you've pre-registered to speak today, please come forward. Great. Thank you. Please state your name and affiliation.

Danni Beer,  
US Cattlemen's Association

Danni Beer with the US Cattlemen's Association. My name is Danni beer, and I'm the third generation to ranch on the Standing Rock Indian Reservation in South Dakota. My family raises beef, and I know what beef is. I know what my consumers expect beef to be. I'm the past president of the U.S. Cattlemen's Association, which is a producer organization made up of the people whose daily lives revolve around the needs of cattle and the health of the land. The U.S. Cattlemen's Association has always been a strong advocate for truth and transparency and labeling. We championed the establishment of a country of origin labeling program for U.S. beef products, which the U.S. courts upheld. We continue to push back against the interests of multinational corporations in favor of consumer rates. That's the core value that brings us here today, truth in labeling. I raise beef and I know the term meat and, more specifically, beef pertains exclusively to a protein food product that was harvested from the flesh of an animal in the traditional manner. I believe that cultured cell-based protein is not what my beef consumers want or expect. Marketing and labeling transparency is critical to the success of the livestock industry. As such, the U.S. Cattlemen's Association believes the labels of beef and meat

should continue to inform consumers that the product is derived naturally from animals that have been raised through the careful stewardship of ranchers. Consumers Union, the advocacy division of Consumers Report, found that the public wants a visible distinction on the label from traditional meat. Based on reporting polls, I think the gentleman from that group said 70% preferred the terms lab-grown or artificial in the title. Also, Michigan State University found that 48% of consumers stated that they were unlikely or very unlikely to consume foods that look and taste identical to meat but are raised on ingredients that are produced artificially. We believe that both USDA and FDA have a role to play in regulating these new products, that Federal Meat Inspection Act states that meat or meat food products should be misbranded, if it's labeling is false or misleading in any particular manner. Allowing cellular based proteins or plant-based proteins to be labeled meat or beef or with the USDA federal meat inspection shield or stamp would be misleading. We believe that the cell culture proteins should be regulated as strictly as beef, but that the product should have their own food category and inspection process not using the stamp or shield. Real meat is more complex than a group of cells growing in a bioreactor. Nearly 1.1 billion have been invested into the beef brand. Since 1986, ranchers have been building up beef's brand through a regular investment into a program known as the Beef Checkoff. The program became mandatory for producers to pay into starting in 1988, with each producer contributing \$1 every time a beef animal changes ownership. The mission of the Beef Checkoff program focuses on improving producer profitability, expanding consumer demand for beef, and strengthening beef's position in the marketplace. It is wrong for beef producers to pay to promote a cell culture product, and it is wrong for any part of our Beef Checkoff dollars to be used to promote cell culture proteins either domestically or internationally. The alternative protein industry should not continue to villainize the beef cattle industry. U.S. beef is among the most sustainably produced beef in the world, and we strive to better our cattle and beef product every day. In short, beef is beef.

Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. Do we have anyone else that's pre-registered to make comment today. Any of the groups - A to B to C or to D? If not, I would like to open the floor for anyone to make any final comments before we conclude for the day. If I have any takers, we really do want to hear from you. We appreciate you coming forward and giving your comments today and yesterday, but this is your final opportunity to let us know your thoughts. Well, I do also want to let our webcast folks know that we also welcome your comments. You can certainly give us your written comments on [regulations.gov](https://www.regulations.gov). Please come forward.

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Mike Selden,  
Finless Foods

Co-founder and CEO Finless Foods Mike Selden. Last time, I like halfway promised. I wanted to talk about the lab-grown label again. If you're eating Doritos, these Doritos are tested in a lab facility, uses a technology based in a field called rheology. They use a machine called an Instron, which I know how to use. What they do is they test the crunch, they test the tensile properties of whatever it is they're building in order to prototype the perfect chip for you to eat. We also do our testing and prototyping in a laboratory, but Doritos are not produced from a laboratory, they're produced in a production facility, a factory, whatever you want to call it, and we'll do the same again. If this is lab-grown meat lab grown fish, they are lab-grown Doritos. I hope we all understand how silly that sounds. And then the last thing, this gets brought up a lot, we have no interest in confusing people. We do not want people to accidentally buy what we are producing as a cell-based fish producer. We want people to buy this with intention, and so we do intend to differentiate our cells from the animal-based meats that are already on the market. We believe that what we produce has benefits. For us, producing cell-based bluefin tuna, there will be no mercury. No plastic. We're not using antibiotics. We are not overfishing the ocean. We are not engaging in animal cruelty. These are advantages that we want consumers to know about, and so we have no interest in confusing the things that we make with traditionally or conventionally produced animal-based meats, because we firmly believe that what we produce has advantages. Thank you.

Selena Kremer,  
USDA FSIS Moderator

Thank you again.

Brian Spears,  
New Age meats

Brian Spears, co-founder and CEO of New Age Meats. My last comment. We in the laboratory scale when we biopsy a live pig as we did, we do need to use antibiotics because antibiotics are everywhere. They're antibiotics or it's, sorry, bacteria are everywhere. There are bacteria on your face in your eyes. They're everywhere, so if you take a biopsy from an animal, you do need to use that. Now, when we're at the laboratory scale, that's the time when we're using that. When we scale that to production, we don't use that. So at scale, our processes will be antibiotic free. Thank you.

Selena Kremer,  
USDA FSIS Moderator

Thank you. I do want to let folks know, please come forward. Please state your name and affiliation.

Kelley McGill,  
Food Law and Policy Clinic

Hi, my name is Kelley McGill, and I'm a student at Harvard Law School and in the food law and policy clinic there, but I'm speaking as an individual right now, and, to me, we've heard a lot of discussion today

and yesterday about these values of transparency and consumer choice. We've heard that from both the cell-based companies traditional growers, and it seems like we're all basically in agreement that we want consumers to have choice and for these products to be transparently labeled. If that's truly the case, why not label them with more information rather than less? Instead of taking away words like beef, why not allow for differentiation on a packaging label, such as with the terms "traditionally harvested beef" or "cell cultured chicken" or however the industries choose to do that, but allowing the differentiation to happen with more words and with clearer words rather than fewer words. Thank you.

Selena Kremer,  
USDA FSIS Moderator

Thank you. Please state your name and affiliation.

Lou Cooperhouse,  
BlueNalu, Inc.

Hi. I'm Lou Cooperhouse, co-founder/president/CEO of Blue Nalu, a company producing a cell-based seafood. Just want to support my colleagues in the cell-based seafood industry a disappear. We heard a few analogies along the way, and I was just thinking about one this morning. It's absolutely illogical to think that cell-based meat, poultry, or seafood is not what it is. It is meat, poultry, or seafood. Clearly, absurdly, very supportive using a descriptive term, and let's use an analogy of something that we all grew up with: the peanut butter and jelly sandwich. What are the three components of peanut butter jelly sandwich? Peanut butter, jelly, and bread. What's peanut butter? It's not butter. It's not a dairy product containing up to 80 percent butterfat by turning fresh cream in milk. It's modified peanut butter, like cell base meat? What else is in there jelly? Jelly traditionally was a spreader preserved from fruit juice and sugar. Now there's pepper jelly. The fruit farmers weren't complaining about using peppers in there, and the dairy farmers obviously haven't complained enough about the fact that peanut butter does not come from a cow. Bread, the third component, made from typically dough with flour and water usually leavened by yeasts and baked, but now there's flourless bread, there's yeast free breads. Those are descriptive terms that help you make a choice. We are advocating to give consumers what they want. They want a choice to make. Not just eat meat poultry or seafood but have a variation on that theme just like they do with variations of everything that we eat every day. In closing, just want to say we're all about transparency and providing the proper communication that allows consumers to choose a more sustainable, ethical, desirous product for them that will continue to consume meat, poultry, and seafood. I'm a meat-eater, I'm a fish eater, but I'm about making more sustainable choices and educating people to slowly make a decision that's what they'll look very consciously about their food consumption. Thank you.

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Selena Kremer,  
USDA FSIS Moderator

Thank you for your comments. Do we have anyone else that would like to come forward and comment? We also do want your written public comments. For the folks out there listening by webcast yesterday and today, you're welcome to submit your written comments to the docket. The comment period closes on November 26. In addition to anyone that's spoken here today, please feel free to submit your written comments as well. If you think of anything after you leave this session today, we would really like to hear from you. Any final takers? Okay. With that I would like to ask Mr. Paul Kiecker, the Acting Administrator of FSIS, to close out today's meeting.

Paul Kiecker,  
FSIS Acting Administrator

I want to thank everyone for their comments that they've made. I want to thank everyone from FDA and USDA that participated and presented information. And I want to thank everyone that has participated by the web. And I want to thank everyone who made this happen, so that it appears to everyone that these kind of events just happen by themselves. Everyone that was involved in setting it up, we really greatly appreciate that, and I think we should give everyone a round of applause. Thank you for your comments. They will be added to the record, and we appreciate everyone's insight into this. We appreciate your comments and your concerns that you've raised. And I want to close out by letting you know what the motto is of Secretary Perdue, and that is to 'do right and feed everyone.' And I think there's a message here for everyone involved regardless of your thoughts on this new technology, one way or the other. Thank you all for everything that you do, and we really appreciate all the hard work that everyone does. Thank you very much.