

Selena Kremer,
USDA FSIS Moderator

Okay, let's go ahead and get started with Session Three today, Strategies to Address Potential Hazards and Provide Appropriate Regulatory Oversight Frameworks for Cell Culture Technology Products derived from Livestock and Poultry. Our first speaker today is Dr. Phil Bronstein, Executive Associate of Regulatory Operations in the Office of Field Operations at FSIS. Dr. Bronstein.

Phil Bronstein,
FSIS OFO

All right, thank you everybody. I have a few slides here that you've already seen before in my talk earlier if you were here this morning, but I'm going to use them to touch on some other things about HACCP. As I told you briefly before, there are two major steps for FSIS at regulated establishments. The first one is to get a grant of inspection, and during that grant of inspection we are looking for Sanitation Performance Standards. We're looking for sanitary SOPs (SSOPs) and we're also looking for a written HACCP plan. All those things need to be in place for us to be comfortable to even give you a grant of inspection, so that you can start your production. The HACCP principles, according to the lore that I know of, HACCP came from NASA and it was used in the space program. It was to make sure that that the shuttle and the rockets were actually able to perform their mission to the highest level possible and get the astronauts back from space as safely as possible.

In 1994 we published our draft HACCP rule, which basically took the HACCP principles and applied them to food safety. We accepted public comments and we made some changes. The final rule was in 1996, and we implemented HACCP, more or less, in all our establishments by 1998. It's been about 20 years and I think, by and large, the basic HACCP principles for FSIS haven't changed all that much. We have made tweaks, especially on some rules, with a couple of extra rules that we have since developed guidance materials and other directives and notices. We have interpreted the HACCP rules a little bit differently from time to time, but I think overall, that the HACCP principles served FSIS well and I think that one of the key tenants is that it emphasizes why we need to understand the hazards.

As regulatory agencies, we need to be as proactive as we can. That's why meetings like this are so very important. We try to get ahead of as many hazards as possible, but it puts the onus squarely on the industry to look at their own process, look at any unique hazards that may be necessary and that may crop up in their own process, and then develop critical control points and critical limits so they can they can manage the hazards in their own process. Then, with the government agency coming in to verify that those things make sense and then a validation

of your plan. I think it's a really robust system. I really think that these sorts of meetings are great because we can openly discuss what hazards are out there in this space, but we're always going to miss something, and we don't have to try to get everything on the first pass because of the openness of HACCP and FSMA, for that matter. The principles are the same with FSMA in that the onus is on the industry to identify the issues in their own establishment, so that we can mitigate them.

In the grant of inspection we're looking for the general condition of the of the facility, whether that's a slaughter facility or a processing facility We're looking for things like potable water, rodent control, acceptable sewage control; we're looking at their sanitary operations, what chemicals they're using, if they are using them safely. We check to see how they are monitoring their usage, and monitoring their effectiveness in the process, and that's a part of the SSOPs. What our inspectors are doing on a daily basis is verifying that the establishment is executing their SSOPs on a daily basis. So, what does pre-op look like? Are they conducting all their controls at the frequencies specified, and whether daily, and what are the daily implementation records out there? Looking for any deviations, looking for corrective actions when there are deviations at the establishments.

I'll quickly go over the seven main tenants of HACCP. The first one is conducting the hazard analysis: microbiological, chemical, and physical hazards. It's the onus of the establishments and on the owners to think about their process and understand what hazards there are and then think about what they can do, where they can control these hazards, and what are the appropriate parameters they need to put in place to make sure, at their critical control points, they're controlling these hazards.

Then, establishing monitoring procedures because we need to make sure they're meeting those critical limits and then also have corrective actions in place, if needed. If there are deviations, what are they going to do now? If you have a heating and cooling deviation, which may allow for the outgrowth of bacteria, or you have the wrong formulation of a product so that you have higher levels of one chemical or one food additive, is that safe? If so, how are they going to mitigate any of the ill effects we might see from that. Finally, because we can't be everywhere at once, it's key to both FSMA and to HACCP to have recordkeeping and documentation procedures. The regulatory agency needs to look back over through time and come back and say hey what how was this yesterday, when I wasn't able to get to this process what happened over here and verify with that.

One of the key pieces is the validation of the HACCP system. We do allow establishments, whether that is through a development of a HACCP plan or an addition of a new technology process, or intervention, we allow them to implement in their establishment. Then look, collect data, and then show us that their new process or procedure or their HACCP system, in general, is performing as they think it should in their written systems. So, those are the major points of HACCP and that's basically what I wanted to reiterate to everybody and tell you prior to us discussing this further.

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Thank you, and I'd like to introduce Jenny Scott, she's a Senior Advisor in the Office of Food Safety at CFSAN in FDA; Jenny.

Jenny Scott,
FDA CFSAN

Thank you. This morning we've actually already covered some of the strategies to address potential hazards and the appropriate regulatory oversight framework. Phil and I are just setting the stage for the comments that we expect people to make about preventive controls and the inspection process. Phil talked about HACCP and Sanitation Standard Operating Procedures as they apply to meat and poultry. FDA actually has some HACCP and SSOP regulations, as well. These apply specifically to juice and to seafood products, but I'm going to focus more on this key regulatory framework component which we got from our FSMA, the legislation that was promulgated that gave us the hazard analysis and preventive controls requirements.

As indicated this morning, we wrapped the preventive controls requirements into an update of our current Good Manufacturing Practice requirements. So, we have this part 117 regulation with a very long title of Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. First, some of the key Good Manufacturing Practice requirements that could be applicable in this situation of cell cultured products.

First, our GMPs require appropriate quality control operations to be employed to ensure that food is suitable for human consumption. Raw materials and other ingredients must be clean and suitable for processing into food and all food manufacturing processing packing and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, for allergen cross contact, for contamination of food, and deterioration of food.

Then, finally, individuals engaged in the manufacturing processing packing or holding of food must receive training in the principles of food hygiene and food safety. Now, this is a very brief synthesis of something that takes up several pages in the Code of Federal Regulations. Turning to the hazard analysis and risk based preventive controls, facilities that manufacture process pack or hold human food must conduct a hazard analysis for known or reasonably foreseeable biological, chemical, and physical hazards. This hazard analysis applies to the raw materials and other ingredients as well as the process; so, they must determine whether there any hazards that are associated with anything they're using in making the food, as well as in the processes that are applied to making the food, and this includes determining whether contamination of foods with environmental pathogens is a hazard that warrants a preventive control. The hazard analysis leads to the identification of those hazards that are significant enough that they must have a preventive control applied and the firm must implement those preventive controls, which would include process controls; that would be controls that they take during the processing of the food, allergen controls, sanitation controls, and any other needed controls, as well as having a recall plan.

These preventive controls are applied at critical control points, just as in HACCP, but it goes a bit beyond HACCP, in that there are also other controls that may be applied at places other than critical control points and those are very important for food safety and those are part of the preventive controls requirements. Facilities must monitor and verify the preventive controls and take corrective actions when necessary. The verification activities could include sampling and testing the food, or in processed food, and it could include environmental monitoring to make sure that contamination of foods with environmental pathogens is not likely to occur. The preventative controls rule also requires a facility to conduct supplier verification when preventive controls are applied to raw materials or other ingredients before they're received in the facility, that means the facility is not going to control those hazards, they are expecting them to have been controlled in that raw material ingredient before they receive it, and everything must be documented in records that are available for FDA review. Keep in mind, that the hazard analysis and preventive controls requirement provisions may apply to multiple facilities along the chain, so someone that manufactures a raw material or other ingredient may send it to another company that does and further manufacturing and processing, and then ultimately it comes to the facility that is making the finished product, using those raw materials ingredients.

All along the way hazard analysis and preventive controls have been put

into place. FDA's regulatory framework provides the flexibility to address a broad array of food facilities and manufacturing processes. Keep in mind, that processes that we know today were new at some time in the past. For example, at one time, aseptic processing was new, high pressure processing was new, food irradiation was new, the existing regulatory framework has provided for oversight to ensure the safe use of these processes and the foods that they are applied to. The FDA's inspection system is also designed to be adaptable to inspect the broad array of manufacturing processing packing and holding facilities under FDA's jurisdiction. Thank you. [Applause]

Selena Kremer,
USDA FSIS Moderator

Thank you, Jenny. Now we're going to move into another open comment period, just like we did before lunch. This open public comment period is on addressing potential hazards and providing appropriate regulatory oversight. That said, we welcome any comments. So, we do have a series of questions on the slide and these are a few of the questions that you'll find in the agenda as well. There are a number of questions. We do have the two microphones up front here. We have ushers to guide you, and as you'll see in the agenda, we've designed a number of opportunities for you to make public comment, so if you're giving public comment later, this afternoon, or tomorrow as well, don't let that stop you; please come up now if you have additional information to offer. So with that we'll get started please come forward. You'll have three minutes to make your comments and when you do come up, please state your name and affiliation.

Sarah Sorscher,
Center for Science

Hi, this is Sarah Sorscher again with Center for Science in the Public Interest. I'm going to be reading off the screen here, but I'll also be giving public comments this afternoon and I just wanted to focus mainly in this section on the pre-market approval aspects of this question.

Although, certainly, there is a need for a HACCP plan and process control and frequent inspections with these products. You know, as we think about the system with what pre-market approval should look like, it's really important to recognize that the final system has to be good enough not just to satisfy regulators in industry that these products are safe, but also consumers and sometimes that's a different question. We see a strong analog here with genetic engineering, where you had a new technology that didn't fit well into existing regulatory framework and consumers didn't fully understand it or trust it. What we saw with GE (genetic engineering) is that industry can believe that technology is safe, and regulators can agree that the technology is safe, and that doesn't

necessarily translate into consumers also believing it. Consumers have pretty roundly rejected the idea that GE technology is safe, and in order to win them over, you have to look back at where we were twenty or thirty years ago and think about what we could have done differently to win over consumers. I think a key component of that is knowing that regulators are there providing the review that consumers can trust.

So, what does that review look like? Well, for one thing it should be comprehensive and mandatory. We shouldn't have a sense that companies are opting in voluntarily to a process. They should be required to undergo review before they market a product. It should be independent. The final decision about whether products can be marketed should be made by a regulator who's charged with serving the public interest, and it should be transparent, meaning that evidence that's used to make the approval decision is publicly available. The existing regulatory structure we have for approving new food ingredients isn't great at accomplishing this. It was designed for food additives, which is distinct chemicals added to foods and it wasn't designed to vet entire new processes and this has led to difficulty with GE, difficulty with nanotechnology and that's why CSPI has long advocated for an act of Congress to create a new process that would be tailored to new technologies for approving them.

One of the most problematic parts of the current system is that it allows for FDA approval. Actually FDA does not have to approve a new ingredient if it's generally recognized as it's safe, and in fact, manufacturers can make this determination internally and they only need consult with FDA on a voluntary basis. This is not appropriate for a new technology because you can't have something as generally recognized as safe (GRAS) if it doesn't have a history of safe use or well documented published literature showing it safe. It's particularly inappropriate for cultured meat because as we saw this morning, and as discussed at the science board meeting, there is not a scientific community that's out there that really understands these products. We are all scratching our heads at what they are and what their safety could be. We think the GRAS process would be inappropriate. I've run out of time, so I'll save the rest of my comments for this afternoon.

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Thank you for your comments. Our next speaker.

Jessica Almy,
Good Food Institute

Hello, I'm Jessica Almy. I'm the Director of Policy for the Good Food Institute (GFI) and as my colleague told you earlier, we're a think-tank that's dedicated to a better future of food, and as such, we're very

enthusiastic about this technology, and I would respectfully disagree, with some of the comments that Sarah just made, despite our common background.

I came to GFI from the Center for Science in the Public Interest. I wanted to share with you that we have a team of scientists who are closely looking at this technology and there's a wealth of information available. My colleagues and I have copies of this article, which was published in *Food Technology Magazine*. We're delighted to share with you, just come up and see us. It goes through the process for creating cultured meat. The message I would share with USDA and FDA today is that no new regulations are needed. As we saw this morning, FDA has adequate precedents to address safety pre-market. And as Dr. Bronstein and Miss Scott just elucidated, both agencies have approaches to hazard analysis and preventive controls that include recordkeeping and inspection.

I'd like to echo Lou Cooperhouse's comments this morning, that the existing systems for preventive control could be applied to cultured meat. I think I raise this for two reasons. The first is that I want to encourage FDA and USDA to continue the dialogue with each other and with stakeholders to develop a clear regulatory path to market. I've been heartened by the comments of both Secretary Perdue and Commissioner Gottlieb that we need bright lines for the industry so that they know how to go through this regulatory process. I would say that the first characteristic of a bright line regulatory process is a single point of entry and I think we're starting to hear that FDA may be an appropriate single point of entry for the companies to work with as they're going through the regulatory process.

The other reason I raise it is that right now, in Congress, there's a spending bill, which includes a provision that would require USDA to promulgate regulations for this industry, and it's really important given the important work that's happening today, yesterday, and will continue tomorrow, and into the future, that Congress know that no new regulations are needed. The two agencies are working productively together and with stakeholders and groups that represent consumers. I would encourage FDA and USDA to let Congress know about the progress that they're making so that this unnecessary provision in the spending bill can be cut. Thanks for the opportunity to address FDA and USDA and the folks who are in the room on this really important issue. I'm excited about the better future of food and thank you all for the part that you're playing in bringing that about.

Selena Kremer,
USDA FSIS Moderator

Thank you for your comments. Our next commenter.

Thomas Gremillion,
Consumer Federation
of America

Hi, Thomas Gremillion, Consumer Federation of America, I'd like to build on what Sarah Sorscher from CSPI said. As I said before, I think the inspection system for these products should be informed by a pre-market approval and a pre-market safety assessment. That assessment should be made by government regulators in a transparent process that is free of conflict of interest. One candidate for a pre-market approval programs is the food additive petition prep process, that Dr. Fasano spoke about earlier this morning. I also talked about the food contact surface approval process that doesn't involve rulemaking and maybe that would be an avenue to explore. Something that that could be maybe more efficient, more expeditious, but not involve industry self-regulation, which is kind of what we have with the GRAS process. In the slides there was the statement that the quantity and quality of the data supporting a GRAS determination and an approval by FDA is similar and we just don't agree with that.

There're a few reasons we think GRAS is inappropriate for cultured meat and I think it's worth reflecting on; how your typical consumer might respond to the question "is meat produced by *in vitro* cultivation of animal cells generally recognized as safe"? I don't think we can generally recognize anything about these products right now. It sounds like there really hasn't been a lot of study of any of these the products that have been the prototypes that have been made. Second, the GRAS process guarantees uncertainty because it doesn't require the companies to notify FDA and so it makes a cumulative assessment of exposure to, say residues of growth hormones that might be in one of these products, very difficult to assess. Finally, I'd say to GRAS, it sets up an inherent conflict of interest. You have the companies hiring the scientists to issue reports that do not need to be published in a peer-reviewed journal, it just needs to be publicly available. This analysis that says the product is safe and if there's data analysis that suggests the product isn't safe - we don't hear about that. I think my time is ending and I just want to reiterate what Sarah said about having an approval process that gives consumers confidence in these products. Thank you.

Selena Kremer,
USDA FSIS Moderator

Thank you. If anyone else would like to come forward, we have all of the staff and the scientists from FDA and USDA in the room today so we'd really like to hear what you have to say. This is your opportunity to make comment and it's open to anybody right now, so you didn't have

to pre-register for this, so please feel free to come forward and let us know what you're thinking.

Michael Hanson,
Consumer Reports

Hi. I have a formal comment, so I'll do it now. My name is Michael Hanson. I'm a senior scientist at Consumers Union the advocacy Division of Consumer Reports. There are two basic ways to produce lab-grown meat. One by proliferating existing muscle tissue *in vitro* or via a scaffold-based system which involves growing cells around a specific structure that cells attach to. The former system using skeletal muscle explants is not currently economically viable for a number of technical reasons, such as a lack of blood/nutrients circulation in the explants. The latter or scaffold-based system is more technologically feasible and often involves culturing suitable stem cells from various tissues so that they proliferate attached to a scalpel to then grow and differentiate into muscle cells when fused with a culture medium in a bioreactor. This method appears to be the one that is moving toward commercialization today.

The source of cells may pose a safety problem. The primary cells, stem cells, satellite cells, can be derived from repeated biopsies of select animals, which means that a collection of animals will be needed. These primary cells can also be derived from cell lines, particularly ones that are immortal and can proliferate indefinitely. As a team of U.K. scientists pointed out in a paper published this year, research is needed on quote, "the safety of ingesting genetically modified cell lines as these lines exhibit the characteristics of a cancerous cell which includes overgrowth of cells not attribute to the original characteristics of a population of cultured primary cells," end quote. FSIS does not allow cancerous lesions or tumors to enter commerce or the food chain. 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. In order to assure the safety of lab-grown meat three things must be assured.

First, the safety of all the chemicals and other ingredients needed to get the animal cells to grow and differentiate: nutrients, growth factors, hormones, and differentiation factors often, including fetal calf serum, antimicrobials, and also materials to make the bio scaffold, etc. should be evaluated and their use regulated, perhaps as food additives or processing aids.

Second, since there is a huge potential problem from contamination of cell lines and our growth culture medium with pathogenic bacteria, viruses, fungi, and mycoplasma cell cultures, unlike living animals, do

not have a functioning immune system. Therefore, there needs to be continuous monitoring of the cell lines and growth media bioreactor for these contaminants and some sort of standards established to assure safety. Our position is that bacteria, fungi, and mycoplasma that are human pathogens should be considered adulterants.

Third, there should be close oversight, continuous inspection of production facilities to ensure they're operating in a safe manner. How regulatory responsibility should be divvied up between FDA and USDA as an open question. Safety of the production inputs may best be handled by FDA. However, for the reasons Sara and Tom have said we don't think GRAS is appropriate for that. As for the safety of the operation of the production facilities, this may be an appropriate role for USDA FSIS, who has inspectors in all the slaughter facilities during production in facilities that require continuous inspection.

In sum, Consumers Union appreciates the opportunity to comment. Cultured meat products should be required to go through a pre-market safety assessment and the GRAS process should not be used. Cultured cell lines and growth culture mediums should be continuously monitored for contaminants and standards set to assure safety. There should be continuous inspection of production facilities to ensure that they are operating in a safe manner. Thank you for the opportunity to comment. We will submit detailed written comments to the docket. Thank you.

Selena Kremer,
USDA FSIS Moderator

Thank you for your comments. Do we have anyone else that would like to come forward today? This session is open to anyone. We have a number of questions in the agenda talking about if you have comments on preventive controls, tools, what are the ways to assess these hazards. We'd really welcome your insight today; no pressure. If you're also making a formal public comment later this afternoon and you'd like to do that now you're welcome to come forward at any time. We really set up that formal comment period and had folks pre-register so that we would we could make sure that everyone that wanted to speak had the full opportunity to do so. That's really what today and tomorrow are about. We've got a number of open sessions to hear from you, whether you'd like to wait for the formal comment period or come down now. Please come down now.

Rhonda Miller,
American Meat Science
Association

I'm Dr. Rhonda Miller with American Meat Science Association (AMSA) and these will be my formal comments. I was in 1B. As the American

Meat Science Association is the organization that represents scientists that generate, disseminate scientific information about meat science for producers, consumers, and regulatory agencies. AMSA recognized efforts in the commercialization of cultured animal tissue from cells in a liquid medium with the goal of producing meat without harvesting animals. The AMSA *Meat Science Lexicon*, which is a scientifically peer-reviewed published journal article, states that, “to be considered meat, cultured animal tissue must result in a product that is comparable in composition, functionality, and sensory characteristics to meat naturally derived from animals.”

To-date, there's no public information or product for independent scientific evaluation to determine if cultured animal tissue product is similar in composition, functionality, and sensory characteristics to meat. It's imperative that labeling and safety assurance systems are the same and have the same rigor, regulation, and oversight as for conventionally produced meat. Consumers need full disclosure and transparency on labeling. It would be misleading and confusing to consumers if the labeling requirements were not the same. Safety oversight through HACCP inspection, food security, and labeling regulations should be the same. Substances used in production of cultured animal tissue need to the same rigorous evaluation of approval process to become GRAS. Scaffolding materials that are food grade need to be monitored for purity and lack of hazards. Remaining scaffolding should be labeled. Cultured animal tissue should be held at safe, refrigerated temperatures or frozen after the culture phase is completed. There are many meat science unanswered questions concerning cultured animal tissue, as production of product to-date has been limited. Meat scientists have not been able to answer these questions, but are willing to cooperate with the cultured animal tissue industry to obtain answers. Major questions such as how the conversion of muscle to meat when animal cultured animal tissues removed from its life supporting environment. Questions about color chemistry, nutrient content, amino acid content, micronutrients, protein functionality, product performance, microbial growth, pH, and variability in pH, protein and water chemistry, need to be answered to make sure that the resultant product performs like meat.

Because cultured animal tissues have not been fully characterized, AMSA is determined that there is not enough scientific information to conclude that cultured animal tissue should be called meat. Appropriate categorization should be determined when these food products become available for rigorous independent scientific evaluation to determine if cultured animal tissue should be called meat. Research by scientists is urgently needed to characterize cultured animal tissue for human

consumption as this technology is commercialized. There is a willingness for this cooperation between cultured animal tissue companies and AMSA members, but product availability is limited. AMSA strongly supports the production and marketing of safe, healthy, and accurately labeled meat for human consumption as required by current regulations.” Thank you for the opportunity to comment.

Selena Kremer,
USDA FSIS Moderator

Thank you for your comments. Our next commenter.

Erica Meier,
Compassion Over Killing

Hi, my name is Erica Meier, and I am the Executive Director of Compassion Over Killing. We are a national farm animal protection organization and we represent thousands of consumers who are extremely concerned about the welfare of billions of animals used for food every year. Our mission is squarely focused on the negative consequences both for people and animals of our current system of animal agriculture, which is ethically, economically, and environmentally unsustainable and it externalizes heavy costs to be borne by all of us. I want to thank the agencies for hosting this meeting and allowing me to share my comments regarding the use of cell culture technology to develop products derived from animals, which is commonly referred to as clean meat.

Compassion Over Killing conducts undercover investigations to give consumers a glimpse of what happens to animals on industrial factory farms and inside slaughterhouses. In the past year, one of our investigators worked inside a Tyson food chicken supplier in Virginia. We found birds who spent their short lives crammed by the thousands into large windowless sheds. We saw workers violently kicking, slamming, and throwing live birds. Chickens were run over and crushed to death by forklifts as employees worked to round the birds up for slaughter, and on top of these awful conditions, many birds suffered from painful leg injuries and other deformities because they have been bred to grow rapidly large in an abnormally short period of time to yield the most meat as quickly as possible. Upon their arrival at the slaughter plant, these animals face a gruesome death. In 2015, we conducted an investigation inside a North Carolina chicken slaughterhouse where our investigator documented birds being violently thrown around the facility. Workers forcefully slamming birds into shackles, punching the birds, shoving them, and pushing them while they're still upside down in their shackles.

This is the plight of nine billion chickens every year in the United States. That's nine billion living, breathing, suffering animals and these are not

isolated incidents. Investigation after investigation shows similar mistreatment of animals; including inside a pig slaughterhouse in Minnesota that we investigated that is participating in the USDA's high-speed slaughter pilot program that the agency is now hoping to expand nationwide.

We need real alternatives to the suffering. We need real alternatives to the cruel and inhumane conditions forced upon billions of animals. We need alternatives to artificial insemination, overcrowding, genetic manipulation, long transport, and slaughter. We need an alternative to abuse endured by these animals who feel pain and fear and we need an alternative to the foodborne illnesses and the proliferation of antibiotic resistant bacteria that's common today. We agree with Secretary Perdue's statement that we need to embrace these new techniques and not put up the unnecessary burdens that would shut down or push offshore new technologies, that we provide these alternatives to suffering. Whatever hurdles are between where we are now and a future that can provide a safer, more sustainable and ethical alternative to the meat industry, as it is now, should be aided rather than hindered by regulation and I also know that the agencies are looking for comments on the labeling of clean meat. This new product is made from real animal cells. To label this product regarding anything other than what it is, meat, would be insincere.

I want to I want to urge the agencies not to subject this new industry to unnecessary regulation. Clean meat offers real positive alternatives to eliminate this needless suffering of animals and to provide safe food. Thank you.

Selena Kremer,
USDA FSIS Moderator

Thank you for your comments. Would anyone else like to come forward and make comment during this open comment period? We really want to hear from you today, that's what this meeting is about. This is your opportunity to let us know your thoughts. Please, go ahead.

Amanda Starbuck,
Food and Water Watch

Good afternoon. Amanda Starbuck, Food and Water Watch and these are our formal public comments. I work for Food and Water Watch, a national nonprofit advocacy organization. We are concerned that the federal government's current regulatory framework is insufficient for overseeing the novel technologies and risks associated with cell cultured meat. We urge agencies like FDA and USDA to update their existing frameworks for regulating biotechnology and other novel technologies before allowing any cell cultured products to come to market. The current regulatory framework for new technologies relies

on outdated tools predating the first wave of genetically engineered products. This means that the vast majority of genetically engineered products in market today have been largely treated like conventionally produced foods. They have not been sufficiently evaluated for safety and are not continually monitored for health and environmental impacts. We are concerned that products created through new technologies, like cell culture techniques, will be treated similarly and end up on consumers dinner plates with virtually no federal oversight.

Instead, FDA should conduct its own risk assessments of each and every novel ingredient and product created using cell culture technology and continue to monitor these products once they've come to market to screen for possible adverse health effects. Instead of awarding GRAS status, cell culture products should be regulated under the processes for food additives and potentially even new animal drugs, which would initiate a more rigorous regulatory process.

Similarly, the USDA needs to have a system in place for inspecting the factories where cell cultured meat is being processed to ensure the safety of the products and help prevent outbreaks of foodborne illnesses. The risks of cell cultured meat are not hypothetical. Academics that pointed out that inducing cells to proliferate makes them similar to cancer cells and we don't know whether they are safe to consume. Additionally, the technologies require a sterile laboratory environment but, often relies on antibiotic use. The amount of antibiotics consumed and the question of where they end up, whether as residue in end products or released into the environment, deserves greater scrutiny.

Finally, these highly processed products contain novel ingredients that may pose alert allergic risks to sensitive populations. The regulatory process should also incorporate reviews from other federal agencies, including EPA, which should investigate the risks of environmental contamination that may occur from the production and use of these new technologies. We urge USDA, FDA, and other federal agencies like EPA to first update their existing frameworks for addressing biotechnology and other novel technologies before assessing cell cultured meat. Independent risk assessments, transparency, and engagement of the public at every step are essential components of a rigorous regulatory framework. Thank you for the opportunity to comment today.

Selena Kremer,
USDA FSIS Moderator

Thank you for your comments. Would anyone else like to come forward and make public comment today? We certainly would love to hear from you, even if it's a brief thirty seconds, you don't have to speak for the

full three minutes. I know sometimes three minutes seems really hard to fill. We do have some other questions in the session three agenda, so if you're interested in talking about inspection types or frequency or oversight activities we'd really love to hear from you.

Paul Shapiro,
Author

Good afternoon, Paul Shapiro again. I know I offered a comment this morning, but I offer one more, which is -- that if we think about some of the comments that we've heard about these cell culture products being so novel, I think it is helpful to recall that there are lots of cell culture products, including cell culture animal products, that are already on the market. If you think, for example, about hard cheese right now, nearly all of the hard cheese that we have contains rennet that comes from genetically engineered microorganisms that produce this chymosin, the enzyme that is functional in rennet. It used to be that we got all of our rennet from calf intestinal linings. Now, biotechnology has allowed us to replace that in cheese with synthetic rennet and nobody seems to be that concerned about it. I don't see the alarm bells going off when we think about eating cheese that has that type of cell culture biotechnology in it, and I think similarly, when we use a cellular agriculture to produce the very types of products like that we know that that process has been used for a long time. It's also used for producing insulin for human medicine rather than using calf and pig pancreases. Now we synthetically produce via a cellular agriculture, human insulin. So, I don't think it's as novel.

I think there are some novel aspects to it, but I don't think it's as novel as we might be led to believe by some of the commentary that we're hearing. Thank you.

Selena Kremer,
USDA FSIS Moderator

Thank you for your comments. Is anyone else interested in coming forward this afternoon and making a public comment? The floor is open. Well I'm not going to pressure you, but I'm pressuring you. I'm not seeing any takers so here's what I'm going to suggest, because we are moving next into our formal public comment period and I think we should just take our break a few minutes early. Maybe lunch was a little too heavy for you. I hope you enjoyed the USDA cafeteria, so let's reconvene in 15 minutes so about five or six minutes after 2:00 and we'll just bump the agenda up a little bit, and then this afternoon we'll go into our formal public comment period. Thank you.

Kari Barrett,
FDA OFVM

All right, if we can go ahead and take seats. Welcome back. We are at that point now where we will begin the official, formal comment period.

This is a session that folks have signed up for in advance to offer their formal public comment. They are limited to three minutes, and again, there is a timer up front. If you can be respectful of that, if you've just gone over three and you're wrapping up, that's fine. We appreciate that but do just keep the time in mind. We will run through the categories. My understanding is that people have an understanding, if they're, say for example, in category 1A, and some expectation where they are in the order. I also have tried to mark off some folks who have already spoken, but we will begin. What we'll ask is those individuals who are in category 1A, if they would like to come up and we have the two microphones, so we'll just begin the process. Who's ever in 1A, would like to kick us off. Again, if you'll say your name and affiliation as you begin your comments, that would be great.

Bob Noble,
Iowa Cattlemen's Association

Good afternoon and thank you to both USDA and FDA for the opportunity to provide comments on such an important issue. My name is Bob Noble and I'm here today to speak on behalf of the Iowa Cattlemen's Association, an organization that serves as the voice for Iowa's 30,000 cattle producers. My wife, Jane, and I operate a cattle operation in Northeast Iowa where my family has raised cattle for 122 years. I also have a background in meat science and beef processing, which provides an important perspective for the topic we are discussing today.

Cattle producers in Iowa and across the country take their role in producing safe and nutritious beef for consumers very seriously. From the pasture, to the processor, to the plate, our industry has made investments and improvements at every stage of production to ensure the highest level of integrity of the beef that we produce. We want to ensure that reasonable science-based standards are the basis for the regulatory system of all meat food products, regardless of how they're produced. The Iowa's Cattlemen's Association stands behind the National Cattlemen's Beef Association and other groups' call for USDA oversight for cell culture alternative protein products. With the top priority of food safety, all meat food products regardless of how they're produced should be subject to the same set of stringent physical, biological, and chemical standards. Processors of all meat food products and all establishments should be subject to continuous daily inspection. Current FSIS oversight already requires that meat and meat food products undergo daily continuous inspection and that processing plants incorporate interventions at critical control points to control any hazards that exist. USDA regulation accomplishes this through the concept of Hazard Analysis and Critical Control Points, or HACCP.

Though the risks and hazards may differ between methods of production, HACCP and USDA's regulation reasonably account for these differences. The Iowa Cattlemen's Association supports exclusive jurisdiction of animal cell cultured meat food products by USDA's Food Safety and Inspection Service. However, we do recognize a limited role of the Food and Drug Administration, delegated in the federal Meat Inspection Act. That act references the Federal Food Drug and Cosmetic Act, which FDA is charged with implementing and enforcing. This reference specifically comes with the definition of adulteration, which describes the presence of chemicals that could constitute adulteration. Though the various chemicals used in production of cell cultured meat will require review, determine their safety and maximum tolerances under the Federal Food Drug and Cosmetic Act, the production and processing of the cell cultured meat food products will be subject to the continuous inspection mandate of the Federal Meat Inspection Act.

To put simply, FDA's role in the regulation of these products should be limited to the review of chemicals used, but the production and processing falls under the purview of USDA's FSIS. To conclude, we appreciate that USDA is taking a lead on this important issue, as prescribed by federal law, and thank you for your time and an opportunity to provide comments today.

Kari Barrett,
FDA OFVM

Thank you very much for your comment. Do we have an additional organization from category 1A?

Eric Schulze,
Memphis Meats

I'm going to raise mic a little bit. Good afternoon everybody. My name's Eric Schulze and I'm the Vice President of Product and Regulation at Memphis Meats. Memphis Meats is a research stage cell-based meat company based in Berkeley, California. We hope to commercialize our cell-based meat, poultry, and seafood products here in the United States in the near future. Cell-based meat products are familiar meat, poultry, and seafood products produced *ex vivo*, meaning cells that would normally grow to form edible tissues in an animal are instead grown matured and harvested in a controlled production environment outside of the animal.

As has been discussed over the course of the day, we will need to find new and more efficient ways to feed an exponentially growing global population. Cell-based meats represent a promising way to meet those challenges. As noted in our joint letter with the Meat Institute, highlighted by Secretary Perdue this morning, under existing law policy and long-standing precedent, both FDA and USDA have roles to play in regulating cell-based meat and poultry products. We look forward to

continuing to work with both agencies and other stakeholders in implementing a clear, predictable, and risk-based regulatory framework for these products that fosters innovation, while continuing to assure a safe and reliable food system. Without a clear, predictable, and timely framework, this industry cannot succeed. Any delays in moving forward would jeopardize the U.S. standing in the world as the leader in protein production and responsible science-based food innovation.

We're encouraged by the joint effort between USDA and FDA and clarifying how both agencies would be involved in regulating cell-based meat, as has been noted by both Secretary Perdue and Commissioner Gottlieb and others today, and we appreciate the opportunity to comment on these important issues. The risk associated with cell-based meat products are well understood and can be effectively managed using existing regulatory paradigms and established controls. As is the case for many foods, the primary hazards involve the introduction of potential contaminants at certain process steps or due to failures in control measures. These types of hazards are well understood and have been already addressed in FDA in guidance and other context, as the FDA speakers noted today. We're confident any potential risk can be adequately controlled through material inputs, aseptic and closed containment processes, manufacturing controls, well-established methods, and include characterization and qualification of cell lines and those raw material inputs, and monitoring and verification.

In terms of pre-market safety, FDA has well-established authority and expertise to evaluate the ingredients used in cell-based meat, consistent with long-standing policy. To this end, FDA has a history of evaluating new or novel foods, including those made from and used in meat and poultry products, and USDA has historically provided input to FDA as a part of this process. Given USDA's experience we believe that role should continue. After pre-market safety has been established, the USDA should regulate cell-based meat products, as it does all other meat and poultry products. Applying relevant findings from FDA's safety evaluation. We recognize that the agencies will have to establish an appropriate inspection process, but we have confidence that they can forge a sensible approach based on their respective areas of expertise.

Our primary hope is that the type and frequency of inspections will be tied to the specific nature of the products themselves and that they're not be duplicative or inefficient regulation. We look forward to providing more details regarding these important issues in our written comment and thank the agencies again for their joint effort and clarifying the regulatory system for this important industry. Thank you.

Kari Barrett,
FDA OFVM

Thank you very much. Okay, we'll now move on to the next category which is 1B. We have a commenter from 1B who'd like to come up? Great, come on up. All right.

Mike Selden,
Finless Foods

Last time the mic was a bit too short. Hi, I'm Mike Selden, Co-founder and CEO of Finless Foods, a company that's producing cell-based fish. I already spoke a little bit earlier and so now I'm going to attempt to say things that add more to the conversation rather than repeating myself and others.

One issue that was brought up today was the question of using serum, an example of which is FBS, fetal bovine serum, fetal calf serum, these are all in the same realm of things, and using that in the production process. I want to reaffirm, as I did yesterday, that Finless Foods will not be bringing products to market that use serum in their production, only in the initial R&D process when we'll be setting up our cell lines. This means there is a point where R&D ends for each cell line, our use of serum ends entirely for that cell line and potential risks, such as prions, that are introduced by the use of serum, can be tested for using methods already explained in existing literature. After that point, we will not be reintroducing serum to our process. So past that point, any potential vector for contamination due to agents, such as prions that can be present in serum, will be eliminated and there is no need to do continuous testing for them, because there is a total lack of vectors for introduction. Serum usage in production goes against the mission of our company, because using serum is both not sustainable and involves extreme animal cruelty. It is also different difficult to work with due to its high price, its fluctuations in quality batch-to-batch, and inherent properties that cause stir-tank bioreactors to foam. On top of that, the supply is quite limited. One wouldn't be able to create any sort of mass-market product that uses serum as an input, because there just isn't that much serum produced on Earth, with Earth's current supply chain - environmental issues aside.

In terms of labeling, I'd like to again assert that we cell-based food producers do need to use the terms "fish" and "meat.". To reiterate, if one is allergic to animal-based seafood, that person has a high probability, I would say almost a 100% certainty, that they will be allergic to the seafood produced using our technology. Labeling it in any other way has a large potential of creating a public health hazard for millions of people. Earlier it was brought up that plant-based sausages

sold online shouldn't be able to use the word sausage, although...apparently it can sit on the stage for hours, even though they've been removed. We believe this argument is totally beside the point. As plant-based sausages are created using an entirely different set of ingredients, and so compositionally is quite different, whereas the animal cell-based products we hope to produce are grown from actual animal cells. We're striving to create on a cellular level the exact same fish meat that people currently eat. It's simply a shift in the way by which we produce it.

The comment earlier comparing this to a shift in ice production from being harvested via lakes to being produced in freezers, which are also a man-made invention, a technology, is apt and accurate. This freezer-based ice is slightly different, in that it contains less debris than its lake-based ice equivalent, but both in the end used the term ice, because they are effectively the same product despite being produced using a different methodology. Thank you so much for listening and thank you to the USDA and FDA both, for convening this meeting.

Kari Barrett,
FDA OFVM

Thank you for your comments. Other folks who registered who are in 1B, who would like to give comment? Okay I'm looking around, we're going to move on to 1C. If you are listed for the 1C timeslot and would like to give your comment. Does everybody know what category they're in? I do have some names here, let's see – 1C. Okay, let me call out a few organizations, and it may be that they did give comment earlier in the day and have met that need to give comments. I had Perdue Farms, and I know they did speak earlier. Perdue Farms, wanted to give additional comment? Okay, great. And again, if you'll say your name.

Eric Christensen,
Perdue Farms

Thank you. This is Eric Christensen, I'm the Chief Marketing Officer at Perdue Farms. I thought I was going to get away with my colleague, Dr. Bruce Stewart Brown, and his remarks earlier, but I guess I will lodge a formal comment. First off, thank you again, as everyone has stated, for hosting this session. It's been awesome, learned a lot, and very excited about it. Perdue Farms is a company that is about consumer choice and labeling that empowers and informs consumers.

Obviously, today we know that consumers have two primary choices in protein, that raised from animals for food, and that raised from plants that mimic some of the qualities and nutritional properties of the animal-based protein but contain no animal cells. So, this this third choice is obviously very exciting. I'm excited about it, but unlike the plant-based products these new cell-based products might be for all

intents and purposes, and I say might because I'm not sure, biochemically equivalent, if someone can interpret what that means, to meat harvested from livestock. So, I think that is a big body of work that has to define what does biochemically equivalent mean to the average consumer.

However, if we are able to achieve this biochemical equivalence, in the mind of consumers does it really translate to equivalent, and there are plenty of studies and whatnot that suggest that consumers are needing and asking for labeling that distinguishes between what they know to be a conventionally grown food and that which is not, a different alternative. We agree with that, there's a report by *Consumer Reports*, a well trusted source of information, and they did a survey in June of this year that stated that.

I think at Perdue Farms we're asking to support consumer choice in a couple of ways, two ways particularly. One, that we clearly differentiate cell cultured and artificial meat from conventionally produced meat, with language that communicates the process. We also believe that we should not encroach or attempt to equalize these artificial or cell cultured meat, especially against well-known and established animal types, such as chicken, turkey, pork, beef, and fish. I would say artificially made chicken is not chicken. Those names should probably reserved for the creator. Cell cultured food from chickens, I think is an interesting idea for a label. That would be clear as to what that is, or cell cultured food from fish, might work, too. We believe these criteria are essential to giving consumers the type of information that they need to make their choices. We also think that claims need to be very carefully substantiated and evaluated. Avoid ambiguous claims, like "clean." That's very ambiguous, and we should certainly not label these as natural, given they are not naturally made in accordance with the USDA definition and I think what consumers would expect natural to be; one of which is not minimally processed. These clearly are highly processed.

Safety has been talked about extensively today and we also believe, as Memphis Meats, that the USDA should be the primary regulatory agent, and excited that FDA will lend their expertise to help with that, and that FSIS should be the inspecting body, as animal meat. After all, the USDA has ensured, safe wholesome and accurately labeled agriculture for decades -- or maybe a century. Whether it's growing on a farm, or a ranch, in a chicken house, or even in a lab, and additionally, USDA is probably more appropriately equipped to ensure equivalency as these technologies are advanced outside of the U.S.

So, in closing, one comment for my friend, Paul Shapiro, who is a good

friend, water is an inanimate lifeless thing turning into ice, animals are not and so we need to work on that analogy, and in closing, I am personally very excited about the future, my children will be as well, they are part of that, and I can't wait to eat my first cell cultured product made from chicken. Thank you.

Kari Barrett,
FDA OFVM

Great. Thank you for your remarks. We also had in this time category someone from Morgan State University, is that individuals still here and like to give comment? I'll go on. Food Resource, LLC? Okay, we'll go on to category 1C, so if there is anyone signed up for 1C? Have I done this before? Okay, NAMI, do we have a NAMI representative who would still like to speak? You've given your remarks, thank you. Okay, Texas Tech University? Higher Steaks? Okay, one I know is still here, CSPI, would you like to come up and give your formal comment?

Sarah Sorscher,
Center for
Science in the Public Interest

Thank you for this opportunity to comment, and my name is Sarah Sorscher. I'm giving the formal comments for Center for Science in the Public Interest. We're a food safety and nutrition consumer group located in Washington, D.C. with over 45 years of experience educating consumers about nutrition and food safety and also advocating for a healthier food system. We don't take any funding from industry or grants from the federal government, and we don't have a financial stake in the outcome of today's proceedings.

From the consumer perspective, we're facing a brave new world with a technology that was once the stuff of science fiction, now becoming a reality, and this new technology is arriving at a time when consumers care increasingly about where our food comes from and its impact on the environment on public health and on animal welfare. Cell-based meat offers a new alternative to traditional agriculture, and whether or not Americans will be interested in buying it depends in large part on the work being done by the people in this room today. We appreciate all the care and thought that USDA, FDA, and industry are putting into this public process. It's important for the two agencies and industry to figure out what steps are needed to assure the safety of these products before they are commercially marketed, but as I said earlier, this process has to be sufficient, not just to assure regulators and industry of the safety of these products, but also consumers. We've seen with genetically engineered foods that a lack of mandatory approval, combined with lack of transparency in labeling, has led to a world where many consumers seek to avoid GE crops, in spite of a wealth of scientific evidence that they're safe to eat.

This has a real impact. We've talked to developers who are now reverting to traditional breeding methods, taking over a decade to develop products that could have been completed in one or two years with GE technology out of concerns with a negative consumer response. We think the solution is for Congress to create a new pathway for all new technology and not just cultured meat, but absent of this, we would support FDA's use of the food additive petition process to ensure that every component that makes its way into the final product has been independently vetted.

While FDA has authority over the pre-market approval of cell-based meat, this does not preclude the USDA from carrying out ongoing inspection of cell-based meat, at least for the meat that's derived from animals that it already regulates. As I've noted, the end product should be pathogen free, because this is both feasible and it will meet consumer expectations for these products.

Finally, while we don't think it's necessary to prohibit the use of terms like "meat" or "fish" on these products, it's important that the labeling be clearly differentiated between cell cultured meat and traditional meat, poultry, and fish so that consumers aren't misled by what they're buying. Consumers have demonstrated time and again that we care what goes into our food. With the right action from regulators and industry, that impulse will benefit these new products, and cell base meat we'll have no trouble gaining a foothold in the marketplace, but if you disregard that impulse and ask us to trust an industry and not look too deeply into what we're eating, you'll get a very different response from consumers. Thank you for this opportunity to comment.

Kari Barrett,
FDA OFVM

Thank you very much. We'll now go on to comment category 1D. If you'll say your name and affiliation. Come on up and feel free to lower the mic if you need. You can also come over to this one too.

Holly Gann,
Animal Wellness Action

Hi there. Holly Gann, I'm the Director of Federal Affairs with Animal Wellness Action. Animal Wellness Action supports the development of cell cultured meat, known as "clean meat," as a way to reduce animal suffering and address concerns about how to safely feed the world as the population grows. We recognize that it will take time for these products to become broadly available in the marketplace, and we continue to support humane sustainable agriculture. Currently, 815 million people around the globe are malnourished, as has been discussed a few times today. Hunger has been on the rise for the last

three years and this number is expected to drastically increase as the world's population grows. We must rethink the global food production system. Cell cultured meat is a logical way to address this issue.

It eliminates many of the negative impacts of conventional animal agriculture. It circumvents the basic problem involved in raising animals for food, specifically the intensive resources required, such as water and space, that are required to produce the food to feed the animals. It also helps eliminate the negative environmental impacts of animal waste and contamination from runoff, the increasing problems with antibiotic resistance, which currently threatens global health, and the public health risks associated with bacterial contamination in meat. Furthermore, it eliminates the animal suffering involved in conventional factory farmed animal production.

The public is beginning to reject conventional agriculture as they become more aware of the cruel practices used in raising and slaughtering animals for food, such as, intensive confinement, where mother pigs are kept in spaces that are so small, they don't even have space to move around. In fact, voters in Arizona, California, Florida, and Massachusetts have all voted overwhelmingly to abolish extreme confinement of farm animals. The U.S. has an opportunity to be a leader by facilitating innovation in cell cultured meat. There may be some industries concerned about this meat taking market share, but that's the history of innovation in a free marketplace, and fortunately, we did not stop cell phone companies from installing cameras in cell phones, even though traditional camera manufacturers probably weren't happy about it.

As for labeling, while these industries don't want to call it meat, we certainly should call it meat because that's exactly what it is. So, we would encourage USDA and FDA to favor competition and not maintain the status quo. Thank you.

Kari Barrett,
FDA OFVM

Thank you for your comments. Additional comments from 1D category? Yes, please say your name and affiliation.

Isha Datar,
New Harvest

Hi, again. My name is Isha Datar, I'm Executive Director of New Harvest. New Harvest is a 501(c)(3) that supports public academic research and cellular agriculture. All of our research is funded by individuals and foundations. Ten years ago, my poultry science professor introduced me to the idea that we could grow meat from animal cell cultures and I've been intrigued and excited by this idea ever since. As we've moved over

generations from extensive to intensive agricultural production systems to create more food from less land, it seemed obvious to me that the next step for food technology would be farming cells instead of whole animals. And because this particular type of intensification removes the need for whole complex organisms, I suspect that producing meat from animal cell culture, rather than whole animals, could result in fewer viral epidemics, fewer threats to food security, and fewer externalized costs to the environment, public health, and animal welfare. Potential benefits aside, there are clearly many unknowns about producing meat from animal cell culture technology, and it is of utmost importance that the oversight hazards and controls of this technology are well understood to ensure consumer safety.

I've dedicated my career to this work, because I believe this transformative technology is inevitable. However, I want to ensure that it enters society in the most responsible way possible. So, it's very exciting to be here today. Overall, I believe there are already frameworks in place from food and drug manufacturing that could assess and manage many of the risks associated with this technology. However, these existing frameworks come from both food and drug manufacturing, and there may be differences in the intended use and the route of exposure of the products evaluated by these existing frameworks and the intended use and route of exposure for a cell cultured meat.

Further, while the frameworks may cover several processes for cell-based meat production, I'm not sure they can cover all future processes, given that there are so many opportunities for novel innovation in the development of cell-based meat production processes. The bringing together of the USDA and FDA for this conversation is thematic of what this field needs. It is inherently interdisciplinary. We need to bring together animal scientists and cell biologists who derive the initial cell lines, we need material scientists to develop scaffolds, we need biochemists to develop the serum-free media, and we need bioprocess engineers to develop the bioreactor systems. We also need meat scientists to understand how this engineered muscle tissue becomes meat.

One theme from yesterday's science board meeting was noting the lack of specific experience and concrete data in this space, as well as a need for learning by doing. The basis of good governance and good regulation is informed by evidence in peer-reviewed research. Federally funded research is an important part of this equation, perhaps because of the novelty of this work, or perhaps because it pulls from areas of science that have not crossed paths before, this research has not received

meaningful federal support. The majority for research in the production of cell-based meats has come from venture capital funded companies or philanthropy funded research organizations, like New Harvest. These funding streams have definitely brought the field to this point. However, for this technology to be fully, safely realized, not just as a product but as a new paradigm for food production, we will need to see more support for academic peer-reviewed research. Perhaps the identification and support of research initiatives that would both equip regulators and minimize burden on innovators could be an important first step for the FDA, USDA, and perhaps the NIH and NSF to work together with the cell-based meat industry.

My organization, New Harvest, as the primary funder of academic research in this space, to-date, with much experience designing interdisciplinary research efforts, would be a keen collaborator and resource in moving this forward. Thank you.

Kari Barrett,
FDA OFVM

Thank you.

Jennifer Houston,
National Cattlemen's
Beef Association

Good afternoon, my name is Jennifer Houston. I serve as President-elect of the National Cattlemen's Beef Association. On behalf of NCBA and our members, we thank you all for hosting this very important meeting for all of our cattle producers. I've been a cattleman all my life. Addition, my husband and I own and operate East Tennessee Livestock Center in Sweetwater, Tennessee. NCBA members are committed every day to producing safe, healthy, nutritious, and affordable cattle and beef. For these reason, it's imperative that the Food Safety and Inspection Service assert primary jurisdiction over cell culture products. While the chemical, physical, and microbial risk and hazards associated with these products will likely differ from the conventional products, any product derived from livestock cells will surely be subject to similar vulnerabilities that can be effectively addressed through FSIS oversight.

Developing and adopting science-based control standards, like HACCP plans and SSOPs, prevents problems before they occur. Simply put, the FSIS regulatory system is effective because food manufacturing facilities are held accountable through daily, continuous inspection. Anti-agriculture activists sometimes argue that there isn't a slaughter process and other differences in production methods mean that FSIS lacks the authority and competency to regulate cell cultured meat products. This is simply not true. These assertions exhibit not only an ignorance of the law, but more importantly, a lack of understanding of

how FSIS does its job and its abilities. Approximately two-thirds of the FSIS plants are further processing plants, and cell-based plants will be treated no differently. Show FSIS you're abiding by HACCP plans, SSOPs, and other food safety requirements necessary to ensure a safe product. FSIS is perfectly capable of applying its existing expertise to the production of cell cultured meat products and is far better suited to ensure the safety of these products throughout the lab-to-fork continuum.

Having said that, the Food and Drug Administration and USDA have a long history of collaboration and partnership in determining the appropriate boundaries of their respective regulatory authorities. The federal Food Drug and Cosmetic Act authorizes FDA to utilize existing review processes as a template to build upon and then the case of cell-based meat FDA should review the various manufacturing processes and the novel substances used in production, to ensure the safety of these processes. Beef producers are more than willing to compete on a fair, level playing field. Remember, in this case however a level playing field is as much about safety assurance systems as it is about nomenclature. Ensuring FSIS has jurisdiction over cell cultured products is the only rational path forward to ensure that result. Again, thank you for allowing me to provide my comments today.

Kari Barrett,
FDA OFVM

Thank you for your comments. Additional folks who have signed up for 1D?

Thomas Gremillion,
Consumer Federation
of America

Hi. Thomas Gremillion, Consumer Federation of America. Consumer Federation of America is an association of nearly 300 consumer groups, established in 1968 to advance consumer interest through research, education, and advocacy. I have already said a lot of what I wanted to say in these formal comments today and will be submitting written comments for the record, but I just want to hit on a couple things that weren't part of the program earlier today.

First, I'd like to say that, American consumers deserve safe nutritious food that is produced in a manner that's consistent with their values, whatever those values are, and I think these technologies are really exciting and respond to some really legitimate concerns out there, but they also raise a lot of new concerns about safety and how we're going to regulate them. With respect to labeling, we submitted comments with the Center for Science and the Public Interest on the National Cattlemen's Beef Association petition to USDA, which requested

restrictions on use of the terms “meat” and “beef,” and in these products and in vegetable-based products and the point we made in those comments that I think are worth reiterating here, is that labeling, like the gentleman for Perdue said really well, labeling should empower and inform consumers. It should be based in evidence of what consumers understand, and what consumer confusion is out there. I have yet to see evidence of consumers going to the grocery store and mistakenly purchasing veggie burgers when they want to buy hamburgers. I think that's something to keep in mind as we talk about what we are going to call these things. I think there's some other issues that need to be clearly labeled if these products actually have some animal serum or products in them that needs to be labeled. If they make a claim to be cleaner or safer, that needs to be defined by the regulatory agencies and clearly labeled. That's it for me today. Thank you for this opportunity to comment and thanks to all audience for listening to me three times today.

Selena Kremer,
USDA FSIS Moderator

Yes, thank you. I just wanted to add, I know you'd mentioned the Cattlemen's petition, I just wanted to clarify for everyone in the audience that that was the U.S. Cattlemen's petition not the National Cattlemen's petition. Thank you.

Kari Barrett,
FDA OFVM

At this point, if there is someone else who expected to give comment this afternoon if you'd like to come on up. Thank you, and again, your name and affiliation.

Justin Oldfield,
California
Cattlemen's Association

Good afternoon, Justin Oldfield with the California Cattlemen's Association in Sacramento, California, here on behalf of our member producers that produce responsible cattle and beef in the State's largest agricultural economy and the fifth largest economy in the world. We certainly appreciate USDA and FDA for hosting this meeting today. I'm going to be brief. Much of what I want to say has already been said. I certainly want to echo the comments made by my former presenters, colleagues of mine in the livestock industry, particularly those of the National Cattlemen's Beef Association. Food safety is an extremely important component of our business. It is probably the pillar that we rest on in terms of ensuring consumer confidence. The industry has invested millions to implement the proper technology to ensure a safe and wholesome beef supply, and although collaboration between USDA and FDA is absolutely necessary, we firmly believe that FSIS must have the primary jurisdiction over the production of cell cultured products.

The use of tainted inputs or poor production practices can ultimately lead to contaminated end products and can disrupt supply chains for not only cell culture products but for the entire beef supply. FSIS must have a day-to-day inspection role in the future production of cell cultured products, and certainly our producers don't fear competition, but emerging cell culture products must adhere to the same food safety standards that we do. Thank you very much.

Kari Barrett,
FDA OFVM

Thank you for your comments. I do have three organizations that are remaining for this afternoon to give public comment. Two I called out before, but I just want to call them out again. Texas Tech University, do we have a representative? Higher Steaks? And the Minnesota State Cattlemen's Association? Okay, we are going to wrap up a little early this afternoon, but before we do that, two things. One is, if there's anyone who wanted to give any last informal comment on hazards or controls, we could take a couple additional comments. If it relates to hazards or controls for today as we close out today's session. Okay, with that, then I'd like to call up USDA to give closing remarks.

Carmen Rotenberg,
FSIS Acting Deputy Under
Secretary

Thanks Kari, and now let's give a big round of applause to our moderators today. I think they did a fantastic job. Thank you to Kari and Selena. And thank you to all the presenters who presented, for the really robust dialogue that we had today - very informative remarks. We really appreciate all that you've done to prepare for this. A couple of just quick notes before we adjourn today. Wing 5 will open at 7:30 a.m. tomorrow morning and we're going to start promptly at 8:30, so please be here if you're planning to attend tomorrow's session. If you need anything this evening, we have a full staff out at the registration desk that can assist you with anything on your way out. Thank you again. Have a good night. [Applause]