U.S. FOOD AND DRUG ADMINISTRATION (FDA)
PUBLIC MEETING

HORIZONTAL APPROACHES TO FOOD STANDARDS OF IDENTITY MODERNIZATION

Docket No. FDA-2018-N-2381

BREAKOUT SESSION BLOCK #2
Industry Innovation

Capital Reporting Company
DATE: Friday, September 27, 2019
TIME: 1:00 p.m.
LOCATION: Hilton Washington DC/Rockville Hotel
1750 Rockville Place
Rockville, MD 20852
REPORTED BY: Sam Varipapa, Notary Public
JOB No.: 3503456

FACILITATORS
Kari Barrett, CPES, CFSAN, FDA
Daniel Reese, ONFL, CFSAN, FDA

ALSO PRESENT:
Mabel Lee, CSO, ONFL, CFSAN
Jan Rothenberg, ORP, CFSAN

PARTICIPANTS:
Shannon Campagna, Van Scoyoc Associates
Doug Hass, Lifeway Foods
Robert Marriott, Internal Revenue Service
Casey Gallimore, North American Meat Institute
Sam Zeller, Unilever
Justin Pearson, Institute for Justice
Eyassu Abegaz, Ajinomoto North America
Ames Perry, Food Resource
Gabriel Wildgen, Researcher, Harvard Law School
John Packman, DLA Piper
Julie Culp, General Mills
Phoebe Wu, Verisk 3E
Adam Friedlander, FMI
Arnim von Friedeburg, CMA Global Partners-German Foods
Elizabeth Derbes, Good Food Institute

P R O C E E D I N G S

SIMULTANEOUS BREAKOUT SESSIONS BLOCK #2

INDUSTRY INNOVATION

MS. BARRETT: I was just saying it's not often that as an agency we get to set aside time and really have this kind of level of discussion with stakeholders, so we really value it, and I just want to thank you for that. But we will officially go ahead and get started. This is the Innovation breakout session, so I want to welcome all of you, and I hope you had a good lunch. I know Dan and I were walking into the room, we're like, oh, we tried to keep our lunch light, but I'm still kind of feeling tired. So, we're going to try to have some energy in the room. If you need to stand up or get some water, feel free to do that during the conversation. But we do understand after lunch can sometimes be a bit tough.

The innovation team today, again, I'm Kari Barrett. I'm a team lead on public engagement in our Center for Food Safety and Applied Nutrition at FDA. And we have Dan Reese, our team leader for product evaluation and labeling team in the Office of Nutrition and Food Labeling at CFSAN, and our flipchart technician is Mabel Lee, who is a consumer safety officer, Office of Nutrition and Food Labeling at CFSAN. And we also have Jan Rothenberg, who is our regulatory counsel in the Office of Regulations and Policy at CFSAN. And just to let you know -- and then we also have our transcriber. So, the reason we're taking so many notes is the flipchart is just to reflect back at really a high level some of the themes that we heard and when we wrap up our session, we'll come back to that. So, that's like some quick feedback. The notes are for the end of the day when we wrap up, that we can kind of feed maybe a little more detail into that when Megan speaks. And then the transcript really is the official record that you guys can reference as, you know, a historical document of this event. So, I want to thank everybody who is playing a role in that regard.

Before we get started, we'd also like to know who is in the room. So, I'm just going to do by a show of hands, you probably did this at your morning session, but if you are with industry, can you just raise your

hand? Just trying to see who's here. Okay. How about representing consumer public health groups? Okay, a bit under-represented. Maybe we'll get some in, or somebody just wants to be contrary and share a view that you think might be held for discussion, please feel free. We do want to look at this from all perspectives and all sides. How about other government officials? Okay. Researchers, academics? Media, anyone from media? Okay. Any other category that wasn't mentioned? Private, excellent. Thank you. Thank you for your time. Law firm, okay. All right, great.

All right. Well, we're going to jump in. And I just want to remind everybody when we're talking about innovation what we're talking about here today. We really are focused on exploring specific changes that the Agency could make to, as we said, the existing standards of identity across categories of standardized food, and that's what we're talking about. We're talking about horizontal changes, and in this session it's to better facilitate industry innovation while still keeping in protections for consumers. And we do want to tie it back that this is, again, part of our larger nutrition innovation strategy and the role that SOI plays. And part of our conversation today will be around the barriers, potential barriers of the standards of identity as well as opportunities.

In your meeting materials there's the write-up. And, again, since you've been through this once already today, you know that there are -- we've offered in this category some of the things that we have heard to kind of help your thinking. We can discuss those proposals. We also have very specific questions that we'll walk through. But there will also be time, if there is something that we didn't cover that you would like to cover, or you would like to offer a thought on, you're welcome to do that.

We do ask that people stay on topic. If you bring something up, and we did have, like, a good comment this morning. It wasn't exactly on topic, but it was helpful for the conversation. We did put it in a parking lot of issues, so just to let you know that we've heard it. But, again, we really want to stay on topic as much

as we can.

We also have some ground rules and, again, you've probably heard similar in the other session. But when you do speak, and what I'm going to do is I am going to run the mic around the room, because I just think that's easier than people having to get up. So, if you want to speak, just put your hand up. But do say your name and affiliation. Again, that's for the benefit in the room, but also for the transcript.

All ideas are welcome, really. Don't hesitate to share. Share as often as you like. We know there will be different perspectives in the room, and that's great. We welcome that. And just be respectful of others. If you -- it hasn't happened yet, and so I welcome it -- but if you had so much to say that I would actually have to cut you off to give someone else a chance to speak, that would be okay.

So, really, this is a nice opportunity to share your view, but also you might hear somebody say something that you hadn't thought of. If you want to expand on that, feel free. This is like a conversation, and, again, it doesn't happen often that we have time set aside for this kind of dialogue.

So, with all of that said, we are going to, as I said, work through the various questions. I'm going to start with the first one and then Dan and I are going to take turns going through them. But the first question is around do standards of identity pose barriers to industry innovation? So, as a general topic area, for example, are they too prescriptive for some of the ingredients that you might be interested in using? So, if you believe that they are a barrier in some way, please let us know your thoughts. If you think that they're not a barrier, welcome that perspective as well. So, let me come back here.

MS. CAMPAGNA: I'm Shannon Campagna. I'm with Van Scoyoc Associates. One example of a barrier used in SOI that creates a barrier is margarine. So, it was originally intended as a low-cost alternative to butter, but then was fortified in order to address dietary gaps, and I think that creates two challenges. I'm watching the flipchart to make sure I'm not going too fast. So,

butter is moving to include more plant oils as it has become more popular, but they aren't required, or they're not using the term margarine, which they technically should be. Then margarine is unable to use -- to really fulfill that consumer need for really simple ingredients and simple ingredient lists, so the nomenclature is antiquated, I think. And that's a great example to kind of kick off the conversation.

MS. BARRETT: Thank you. So, definitely a barrier. Yep?

MR. HASS: Doug Hass with Lifeway Foods. So, industry, I think the general answer to the question is yes, it can be a barrier or not, depending on your particular situation and the particular product. I think it's important, kind of piggybacking on the last comment, that barriers aren't just barriers to entry, barriers to innovation; they can hamstring or constrain products that fall within the standard of identity that when other products in the marketplace dump. And the example in addition to margarine that I talked about in another session and other was the product Lifeway makes, but kefir. Also true of many traditional dairy products. We fall within the cultured milk standard of identity, and kefir is actually, and other traditional dairy products, like lassi or skyr -- we are prohibited -- in the United States, the only country in the world where we're prohibited from calling kefir kefir. The standard of identity requires us to call it kefir cultured milk or kefir cultured low fat milk. We can't actually call it by the traditional name that is used in every other country in the world that's been called by people in Eastern Europe for over 2,000 years. We can't use that name here in the United States. But in terms of innovation who can, there are companies making plant-based beverages that call their products kefir. Simply kefir, not kefir cultured milk, not kefir something else; they have a fermented coconut water or a fermented tea or a kombucha, and they just call it kefir. So, if you are an Eastern European, you know, a person from Eastern Europe, if you're -- or anywhere in Europe, and you're used to -- you're in Ireland and you want to buy kefir and you come to the US and you want to go buy kefir, and

you grab a bottle of kefir off the shelf, you're not getting it. You're getting something else entirely, and it's because the standard of identity constrains the dairy manufacturers in a way that we can't -- we can't even use the name for our product much less innovate in a way that would be productive for consumers. We can't respond to that, so I think you have to go back to the original, what does the code say about, you know, honest and fair, and I think a lot of times the standard's identity creates a straightjacket for certain parts of the industry.

MS. BARRETT: Thank you. And thank you for that example and spending a little time on it. I see lots of hands. I'm going to go up here and then I'm going to come over here.

MR. MARRIOTT: I just want to go back to the example of margarine for a moment and talk about one of the advantages of standards of identity as barriers. In contrasting them to the situation of the states and individual state regulation, margarine is a great example of this because of its historical political and other conflicts that occurred over it that went to the creation of the precursors of the FDA, in that the margarine represented a disruptive technological innovation that was viewed with tremendous skepticism and importantly engendered a number of pseudoscientific beliefs around the product which were rapidly promulgated across the country, including in the form of state bans on the product for several years until those were overturned with the advent of federal regulation.

In the course of considering what role the government plays with any foodstuff and how it's defined, we probably don't want to go back to -- and here I'm going to briefly quote *Smithsonian Magazine* on this, Senator Joseph Quarles of Wisconsin saying, "I want butter that has the natural aroma of life and health. I decline to accept as a substitute caul fat, matured under the chill of death, blended with vegetable oils and flavored by chemical tricks." Generally representative of the tone of the period. It's not really a place we want to go back to.

MS. BARRETT: Thank you.

MS. GALLIMORE: Casey Gallimore with the North American Meat Institute. In the vein of today's theme on horizontal changes, one that applies to many different standards is the restriction on added ingredients for flavoring. Consumers in the marketplace right now want a lot of variety, and the industry wants to give them those options, but we're not allowed in various standards to change the flavor profile. And our belief is that if it's not changing the core identity of whatever the standard is and it's just a different option for flavor, as long as that flavor is appropriately labeled in conjunction with the standard name for the item, it should be allowed.

MS. BARRETT: Thank you. More hands? More thoughts on the barriers? Okay, should we move on to the next question? All right, I'm going to bring it up, so, Dan, if you want and I'll just keep working the mic.

MR. ZELLER: Hi. I'm Sam Zeller with Unilever. We touched on this in the morning session with nutrition, and it has to do with salt substitutes. And one of the barriers is that certain standards of identity are very prescriptive when it comes to the use of salt, specifically, sodium chloride is the only preservative that's allowed. And we talked about this in terms of kind of FDA salt reduction strategy; there's a tie-in there. There's a tie-in with other initiatives in terms of clean labeling and potassium chloride, salt, and specifically that's really not a very clean label to consumers, but potassium salt might be an alternate. So, it's an example of a barrier right now to innovation.

Some of the consequences are micro concerns, if salt, sodium chloride itself is lowered, so I think that's an example of a specific barrier. And maybe broadening our thought across categories rather than just a subcategory of cheese, where salt substitutes might be of interest, I think there are other categories -- dressings is one that comes to mind. Sugar and sugar substitutes, where we might focus on a certain category. Certainly, other categories with regard to frozen dessert and others that might be impacted. So, I just kind of wanted to think a bit more broadly in terms of horizontal changes in terms of how that can be stretched across a

broader spectrum.

MS. BARRETT: I'm really glad you brought that up. Thank you. Any other thoughts on barriers? Yeah, sure.

MR. PEARSON: My name is Justin Pearson. I'm a public interest lawyer with the Institute for Justice, and it occurs to me, I think -- I agree with a lot of what has been said. But also, one thing that I think really hurts innovation, and anytime you have this sort of one-size-fits-all approach, for better or worse, you're going to harm innovation. But I think one of the more problematic aspects is sometimes people will come up with kind of a new and innovative variation on something that already has a standard of identity and they have to label it as imitation, when it's not imitation. It might be slightly different, but it's not imitation. So, by using such a loaded required disclaimer, like the word "imitation," which has so many negative connotations to it, it actually amplifies the harm, where even if you still had this generally harmful regime, it wouldn't be quite so bad if it didn't mandate such loaded terms like "imitation." And so, I think that would be an easier across-the-board fix, is replace "imitation" with something that isn't so qualitatively negative.

MS. BARRETT: Thank you. Thanks for raising that. Yeah?

MR. ABEGAZ: Eyassu Abegaz from Ajinomoto Health and Nutrition North America. I think in reference to other folks that has mentioned about barrier to innovation is one area specifically in use of texturizing enzymes. There is some barriers, for example, sour cream or other dairy products where the enzyme that could be used very narrow specific to rennet, where there are other enzymes, which is microbial fermentation enzymes that could be used and have similar functions. So, that could be applied horizontally as well.

MS. BARRETT: That's one that hasn't come up this morning, so thank you. More on barriers? All right, well, let's jump into the opportunities. Dan, do you want to walk us through question 2 and some of the subparts?

MR. REESE: Yeah. Question 2 has several

subparts. I'll take the first two together because they're similar. We are interested in exploring changes that could be made across categories of standardized foods to better promote industry innovation. We'd like to hear your ideas for specific changes that would help FDA achieve its innovation-related goals. For example, what change or changes could FDA make to existing SOI regulations to better promote industry innovation? And of these, which standardized food or food categories would be impacted by these changes?

So, I think Kari mentioned this morning, here's your wish list; what would you like us to change, if you could?

MS. BARRETT: You wake up tomorrow and you could make the world what you want, what would it be?

MR. PEARSON: I think one thing that would be helpful is to focus on actual consumer deception and not whether something complies with a regulation that might have been drafted decades ago. And I think one way to do that would be to allow anyone to use any standard of identity they want as long as they put other information on the label to explain what it is. So, sometimes labels aren't just one word with nothing else on the label, right? There's all sorts of other information on the label. And if they put other information on the label explaining exactly how their product is different from the traditional standard of identity, and they do so in a way that consumers understand, that shouldn't be against the law. And by allowing them that option, again, as long as they're clear about what the difference is that consumers understand, I think if you allow them that option, that increases innovation.

MS. BARRETT: Thank you for your thought.

MR. MARRIOTT: Robert Marriott. So, is this, to ask directly, is this sort of a shrink-wrap agreement model of food labeling, where there's a paragraph there and you read it and by opening the package you're effectively agreeing to whatever it is?

MR. PEARSON: No, and this is something that comes up quite a bit in class action lawsuits. It's reasonable consumer understanding. If you have one of those giant boilerplate descriptions, no reasonable

consumer is going to understand that. And so not only could they get in trouble with FDA, they're going to get sued by class action lawyers. But that being said, you don't need that in many situations to explain what something is. So, for example, if you put the word "milk" on a product and there is no other language on that label but the word "milk," people are going to think one thing. If you say "coconut milk," they're going to say something -- they're going to think something else. And oftentimes that type of difference can be easily explained to consumers. Not only that, but oftentimes consumers seek them out, seek out those variations in ways that make it very easy to explain to them how your product is different than the standard of identity.

If you have to do -- if you have to write an entire paragraph explaining the difference, then chances are you're not who I'm talking about. But time and time again I see people who are banned from using just very simple variations on terms. You see that quite a bit now with the different plant-based alternative, where, you know, if you just say "bacon" on a label, people are going to think one thing, but if you say "vegetarian bacon made entirely from plants, no animals harmed," that's something totally different. Or "milk," one thing, "almond milk" something else. So, to the extent that someone can do it in a way that a reasonable consumer will understand, which isn't true of all possible products, but for many of them, then that should be encouraged.

MS. BARRETT: I'm going to go back here and then I'll get some of the others.

MR. HASS: I think to kind of piggyback on that, I think that this isn't so much a discussion about innovation. I mean, if you want to innovate, Lifeway -- Doug with Lifeway again. Lifeway has a plant-based product; we call it Plantiful. Chobani has a plant-based product; they call it Chobani. They don't call it yogurt, they call it Chobani. Lots of companies have invented all kinds of names to call their product, and that's an exercise in branding, and there isn't any, as far as I know, Trader Joe's hasn't gone out of business because they call it Trader Joe's almond beverage instead

of almond milk.

I think this is really a question of scope. And in order to get out of the way of innovation, I mean, people can innovate and call things whatever they want, but if we're going to have standards of identity, we need to narrowly define them and say, look, if you're going to use the word "milk," it is this. You know, the EU doesn't have -- it's funny, the EU doesn't seem to have these kinds of issues. If you want brie, there's a specific thing that brie is. Brie is this. You can make cheese; you can call it anything you want. You can say this is something that's supposed to taste like brie. You could make that claim. You know, you can't say that one, but you could say it tastes like cheddar. Cheddar is one, I don't want to say -- you can say it tastes like cheddar. You can do cheddar style, you can say brie style, you can say mozzarella style; you can do those kinds of things. But if you're going to say that it is brie, or you're going to say that it is chardonnay, those are things that are defined. And I think the best change, from my view, that the FDA could make would be to -- if you're going to have standards of identity, stick with them and don't allow deviations and kind of -- if it's not important enough to have a standard of identity, don't, and just go back to focusing on the honest and fair dealing piece of what the code mandates that we do with these.

MS. BARRETT: Thank you. And I think that's raising a good point, too, that it doesn't necessarily have to be one or the other regime, that there may be, in looking forward, some combination of approaches that are taken.

MS. GALLIMORE: To kind of reiterate, the problem with coconut milk or vegetarian plant-based bacon isn't only what does the consumer know. You're right, consumer doesn't think that coconut milk came from a cow, but milk that did come from a cow has very strict standard of identity and coconut milk doesn't. So, all those other strict things that milk has to comply with, coconut milk right now doesn't have to. And it's the same thing with plant-based bacon. I can make -- I can take a pork belly and I can cure it, and I can slice it,

and if I don't do it the right way, I can't call it bacon. But you can take a plant and form it to look like a piece of bacon and call it bacon.

And the other problem, especially with meat and poultry products, but not just meat and poultry products, there's a lot of other commodities that have check-off dollars, and they've spent millions of dollars over the years doing consumer research and marketing their products. And these other products that are imitation products that are using a name that has a standard of identity are benefiting off of those years of research and marketing without putting into any of them.

MS. BARRETT: Yes, I'm going to hand it right over to you.

MS. PERRY: Ames Perry, Food Resource. I think, too, when you have the imitation, what the regulations say is it needs to be nutritionally inferior to the product. And as far as I've seen, there aren't particular guidelines about what qualifies as nutritional inferiority because, yes, you may have a higher protein in this one, but maybe you have good vitamin D in this one, and so I think how can you talk about nutritional inferiority if you're not defining it? And then it almost seems like you have to take it down to a product-by-product basis. You know, if it's a milk, well, it doesn't have the calcium that dairy milk has, but, on the other hand, it's a very good source of phosphorus, for instance, or whatever it is. And so I think there's a lot of confusion even among regulatory professionals, which I am, as to how you define that, and so does it becomes an imitation product or something else?

And another point to calling something bacon that's plant-based, the word "bacon," you can leave yourself open to an FSIS inspector holding your product, because bacon is represented as a meat product no matter -- if you read your immutability, it covers that. The products that are named after meat products can be considered to be meat products, and if they don't meet those standards, then they can be seized, retained, whatever.

MS. BARRETT: Thank you. You raised some good points. Thank you. Other hands up this side? And we do

want to hear on opportunities as well, right?

MR. WILDGEN: Hi. My name is Gabriel Wildgen. I'm a student researcher with Harvard Law School, and we are doing a lot of research right now in food innovation, especially around plant-based foods.

In regards to the comments about milk earlier, I'd like to point out that milk was not something that -- it's not a term that was developed in marketing for the dairy industry. Almond milk, for instance, has been around in English language since around the year 1390 in the English cookbooks. The idea of using almonds for milk goes back a little bit further to Egypt. So, "milk" has widely been applied to other types of, you know, white, milky substances that do not come from a cow's udder for a very long time, not from industry research.

I'd also like to point out, with the comparison to Europe, I'm not very familiar with European law. But I do know that here we have the First Amendment that protects free speech, and we have commercial speech. And the government has no constitutional right to intervene on commercial speech that consumers understand, especially if there is no government interest intervening. And that is the case here, where these are healthy products, almond milk, soymilk, in many ways are healthier than cow's milk, so the government has no constitutional footing to stand on to intervene and enforce a narrow standard of identity for those types of foods.

MS. BARRETT: Thank you for your thoughts. Any more on this side right now?

MR. PEARSON: Thankfully, this gentleman said some of the things I was going to say, so I can keep it a little shorter. But two things I want to point out really quick since checkoff programs were mentioned, and I know that's not what this is about. But it really illustrates the difference between industry stakeholders who represent huge companies and small businesses. Oftentimes, when any government agency talks about industry stakeholders, they're unfortunately hearing from huge businesses, and those are the ones who love checkoff programs. Small businesses hate them. They hate them, because the big businesses want the consumers to think

that something like milk is all the same regardless of where you get it from, and it's the small businesses that want the exact opposite message, and their message is being crowded out by the checkoff programs. So, checkoff programs are a whole other problem.

But then going back to what the gentleman in the back said, any time you take away the term that consumers understand best, you increase consumer confusion. And so, it's not that someone who is selling, for example, coconut milk is trying to trick consumers into buying something that they don't want. Or, actually, a better example would be like the plant-based bacon that was discussed before. It would actually hurt these companies if people thought they had started animal meat. But what happens is when you use that term that consumers understand, that helps improve the consumer understanding of the characteristics of what they're buying. It's not that the consumers are being tricked into buying something that they don't think they're buying, it's that that helps explain the characteristics succinctly in a way that's extremely useful to consumers, and when you take that option away, consumer confusion goes up, not down.

MS. BARRETT: Thank you. I mean, I think what we're -- you know, just reflecting what we're hearing is that standards of identity are full of meaning; they have historically venues in a certain way, we know that. But here we are in the year 2019, in our marketplace we see so much innovation, we see so many different consumer demands. We see a lot of new products. How do we prepare ourselves for the future? How do we keep what we need to keep, to ensure consumer protection, but at the same time allow these marketplaces to become what they will to meet the needs? And somebody said in an earlier session, when you're looking at standards of identity, it's like going to the grocery store in 1960. So, how do we get ready for that grocery store in 2060, you know? So, it's sort of like let's talk about opportunities. What are the frameworks that we need? What are the changes that are needed? Where can we go?

MR. PACKMAN: Thanks very much. I'm John Packman with DLA Piper, and I think the critical

consideration in preventing standards from standing in the way of innovation and protecting consumers from being deceived is to ensure complete transparency in labeling. The historical context is incredibly important here.

So, when standards were created, we had a very simple food supply and a high risk of fraud. In the early part of the 21st century now, we have an incredibly diverse food supply with greater and greater demands being made on it by consumers all the time. And the risk of fraud continues, but it's far, far easier to detect, and so the consumer protection need has changed, and the needs for standards of identity has substantially changed.

So, to pick up on what you were saying about the First Amendment and what you were saying about describing to consumers how the product differs from the standardized food, if you could assure that the label would communicate every material or meaningful deviation from the standard of identity, then consumers would be fully protected.

MS. BARRETT: Thank you. Dan, do we need to come back to you on those last two aspects of question 2?

MR. REESE: Yeah. So, the last area we wanted to discuss in question 2 is, when we are looking at promoting industry innovation, what are the appropriate limits to this flexibility to ensure the standardized foods continue to meet consumer expectations?

MS. GALLIMORE: Casey Gallimore with the North American Meat Institute. One of the things that we proposed in the joint petition with GMA was to allow alternate manufacturing processes. So, I think, to answer your question, when you're looking at increasing flexibility to allow for innovation, you need to look at why the standard was created in the first place, and to make sure that whatever flexibility you're allowing doesn't corrupt that initial purpose in the standard. If the standard is that a consumer will have a consistent product that's going to taste the same, that they're going to know what it's like, that's something that now we have a lot more ability to show with science, that we can use an alternate process and still get the same product in the end. So, that would be -- again, things

like aging, there's ways that we can age products much quicker but get the same effectiveness at the end. There's other examples as well.

MS. BARRETT: Thank you for your specific examples. That is helpful. More comments? Hands?

MR. ZELLER: Sam Zeller from Unilever. I raise the alternate make and novel technologies in the morning session and I still think it merits a lot of consideration. Then as I started to think about it, I struggle a bit, or maybe perhaps challenged a bit by how that would fit in a horizontal regulatory approach. A lot of times I'm looking at specific standards that have very prescriptive technologies that there very well may be alternate ways to go about it. So, I just -- point being is that I struggle to see how that fits into a horizontal approach. I'd like it; I just don't know how to make it work.

MS. BARRETT: Thank you.

MS. GALLIMORE: That's a really, really good point. Again, this is Casey with the Meat Institute. One of the things I need to focus on is being more outcome-based. So, I mean if you think about the same principles that we have for food safety and the thought process between HACCP and the new preventive controls, the end of the day, the product has to be safe, but you get to choose how you get there. And I think those same principles can apply. We need to be more outcome-based. So, if the standard is that the product is like this at the end of it, I think we're past the point of telling you how to do it and just -- if you can prove -- and I think that's something that companies -- you know, if you're going to vary from the standard in your manufacturing process, you need to have supporting data that shows that the product is still the same as what it is on the outside. And I think industry is more than willing to get that data to support an alternate manufacturing process.

MS. BARRETT: Thank you. Some more thoughts on the opportunities, approaches for the Agency to consider in making change? Okay, well, we're going to go -- yeah.

MR. WILDGEN: Sorry, something I raised earlier on the nutrition panel. Sorry for those of you who heard

this already, but it may be more appropriate for here. This isn't necessarily a change in policy that we'd recommend at the Harvard Law School, but we think currently when it comes to using qualifying terms, such as soymilk, rice noodles, quinoa noodles, rye bread, etc., when attached to a standardized term, we know the FDA is currently basically allowing this to happen, and we think that's a good thing for innovation, because we're seeing all these new products emerge that are often healthier alternatives. But what we're recommending is that the FDA clarify that this is indeed the policy, whether it be through a guidance document or some other format. We're still clarifying our own position on that, but it should be some kind of official clarification. And without that clarification, there may be a chilling effect that might be more innovation that is being held back right now, because there might be some players in the industry, or potential players in the industry that are holding back until this gets settled, until it becomes clear that they can indeed use these qualifying terms.

MS. BARRETT: Thank you. And I know that you all are aware that we did go out for that -- we've been soliciting comment on this and are certainly aware that we need to have a policy that's clear.

MS. CULP: Julie Culp from General Mills, and just to build on that. Because oftentimes these same products with standards are then used in mixed foods. So, I think having guidance or clarification from the Agency that would apply both as sold as individual foods, and when added within a mixed food would be very helpful.

MS. BARRETT: Thank you. More comments on this particular set of questions? Yeah.

MR. MARRIOTT: Robert Marriott. There's a set of low-hanging fruit here in terms of setting the groundwork for any set of reforms or modernization to standards of identity. It is articulated in the 2005 proposed rule, which is the removal of redundancies or unnecessary variances between standards of identity that already exist. Even if there are other changes that need to be made to the standards of identity, and certainly a larger scope is being considered here, there is

tremendous advantage in removing some of the material that's built up over time in the current standard library that is a product of decades upon decades of reactive, sort of selective, duplicative material and definitions. And to the degree that the Agency could act purely to resolve those, it seems like they would have less pushback, potentially, that could make the next step in the process easier, whatever that step may be.

MS. BARRETT: Some housecleaning is what I'm hearing. Yes, thank you. More comment on that? You guys are great helping me.

MS. WU: I'm Phoebe Wu from Verisk 3E. We are actually helping the industry to compliance with regulations, so we provide regulation into a database format. So, the challenge we're having is, first of all, the categories of the food is sometimes it's ambiguous between countries, and Codex has very clear four categories than the industry can fitting their particular product into, but the US, the CFR sometimes SOI it's for the imported, other countries food is harder for them to classify their fortified product into particularly the SOI. So, probably this is the area I'm thinking FDA can consider if there is more imported other countries' food, how those food could be classified into SOI.

MS. BARRETT: Thank you. And that really does bring us to the next question, if I recall right, which is about are there other models out there that we should be looking at, whether they're global models, Codex, are there other countries who are doing this right and you want to reference them? We heard somebody in the morning session talk about voluntary industry standards coupled with things like consumer research or certification, some kind of oversight. Could you put together some kind of package like that and maybe bring it to the Agency for review? I mean, what will it take and are there some models out there that we should be considering? So, I'm going to just turn it open to anybody who wants to comment on that.

MS. GALLIMORE: Know it's already -- this is Casey with the Meat Institute again. I know it's already on your mind because you already said it, but Codex obviously is a great one to make sure that we are looking

at when we set standards. Not that we always have to do exactly what Codex is doing. I know the US often takes a different position that we feel better -- is better for our consumers. But Codex and international standards in general are important. We don't want to create barriers to trade in trying to create flexibility.

MS. BARRETT: Thank you. More thoughts on that?

MR. PEARSON: Just really quickly, and I know this gentleman over here mentioned something similar before. But we need to be very careful looking at what other countries do, because they don't have the First Amendment like we do. And it doesn't mean that we can't look at what they do at all, but you need to realize that what works there might not work here.

MS. BARRETT: Thank you. More comments on models that might work?

MR. FRIEDLANDER: Hi. Adam Friedlander with FMI, and I work in food safety. So, my immediate thought is how are the products that our customers, our members' customers purchase, how are they influenced by the claims that are made on the label, so making sure that the food is safe, making sure that it's healthful, truthful, not misleading, etc. But I immediately think of food allergies, and I said this in the earlier session for consumers. But basically making sure that if you do have a standard of identity, making sure that if there is an eggroll, for example, which may or may not have a standard of identity, making sure that the Food Allergen Labeling and Consumer Protection Act is also thought of when we're creating standards of identity. So, that product -- I saw a product and I looked at the back of the label and it said contains milk and wheat, but it didn't contain eggs. So, as a consumer I think, oh, an eggroll should contain eggs.

So, I don't know exactly where that leads to in terms of legality. But if you're saying -- and I'm just thinking off the top of my head -- plant-based milk, as a consumer, is it reasonable to think that this product does not contain milk? And what if on the PAL, if it says may contain milk, as a consumer, is it reasonable for me to think that this product still a precautionary

allergy label, which is not required under FALCPA. So, I think that there are so many conflicting parts of a food label, but we need to think of consumer health as our top priority.

MS. BARRETT: Those are good points. Thank you.

MR. VON FRIEDEBURG: Arnim von Friedeburg, CMA Global Partners-German Foods. If the goal of the standard of an entity is to protect consumers from harm and prevent economic adulteration, why not fold it into FSMA, into making it a preventive control and not having it as a standalone project? Because in the end you can put the onus on manufacturers that leaves more room open for what an identity is. As acknowledged, many of the food identities are completely overdone, from the 1950s, they don't know -- they don't need to be there anymore. If the goal is to take people into more healthful diets and healthful lifestyle, maybe the standard of identities have nothing to do with this, really, and it's a different topic that could be considered with labeling or with efficacy advertising. So, just a thought.

MS. BARRETT: Thank you.

MR. HASS: I think one of the other opportunities in the model is to pick a model. You know, we regularly engage -- Doug with Lifeway again, by the way. We regularly engage with USDA, and we hear one approach; we engage with CFSAN and we hear a totally different approach. And then when you get into -- you know, we've heard a lot about First Amendment, which really doesn't have anything to do with standards of identity, but more with honest and, you know, truthful communications about products. That's a whole other agency entirely; that's the FTC. And they take a completely different view from FDA. And you have courts, also, coming in, and so you've got the plaintiff's bar that will -- and public interest firms that bring issues to judges. And so now you have kind of a living, breathing case law out there, and in many cases we've seen over the years in our industry, we've seen judges begging the FDA to say something, anything. Kind of goes back to that earlier comment about have a policy, tell us what it is.

We were in a case that was stayed for three years while the judge actually sent a letter to the FDA saying when are you going to do this, and after three years he finally gave up and just decided something. So, now we have another body of case law that says something different than maybe what the FDA wanted, and it's different than what the USDA says, and it's totally different than what the FTC or, you know, if you're going to go before one of the advertising bureaus, they've got their own other set of case law. So, the problem is we just have too many models, so I think kind of -- I think it was heartened to hear that the 2005 regulation is being reconsidered, and I think that's one of the biggest opportunities is to find one voice to speak with on these issues and not leave industry and consumers and everybody else sort of confused about what is the right -- what is the policy.

MS. BARRETT: Yeah, those are good points, and it's been raised up that there are so many standards of identity, and the work involved in all of those. And, again, bringing us back to is there some way to address this in categories of food or categories of approaches, or something of technologies, whatever those bins are, so that the rule-making or regulatory process itself doesn't take so long, that we can be maybe more nimble.

MS. GALLIMORE: Again, Casey with the Meat Institute. I know someone earlier brought up qualifying terms, and I think that is a -- it's a good option, especially for a horizontal approach. And it would be much better than the alternative that we have right now, which is we have arbitrary qualifying terms that don't technically mean anything in the regulatory sense. So, using a horizontal approach to define some of these qualifying terms is a great option to say, okay, if you're not making something quite to the standard, even if it's this standard versus this standard or this standard, it would be something similar to reduced fat or low sodium, or qualifying terms we already have in the marketplace, adding those for some of these new, innovative ways that we're making food so the consumer has some kind of consistent rule when they see these qualifying terms on products.

MR. ZELLER: Sam, Sam Zeller from Unilever. I guess some of the conversation sparked a thought, which is why I think we're here. FDA already has a regulation, right, for statements of identity, right, where we're first compelled to use a standard of identity if one exists, followed by a common and usual name or, in absence, then an appropriately descriptive term. So, I'm kind of going back. Our focus has been on standards of identity here, right? But is there a way, in your reference to the industry list, is there a way that we can maybe more solidify common and usual names?

I was sitting next to a gentleman from the Tea Association, that tea is a common and usual name, but it's applied to a beverage produced from the leaves of *Camellia sinensis*, right? So, how do we establish that, and then we can use appropriately descriptive terms to differentiate other beverages, whether they're herbal teas or such. So, not necessarily right on point here, but I still think it's already a bucket that FDA has in terms of here's an SOI, here's a common and usual name, here's an appropriately descriptive term, and then we can go on to say and that appropriately descriptive term should not be confusingly similar to other foods, right? Let's use what we already have.

MS. BARRETT: Anyone else on this side?

MR. MARRIOTT: To the point of products without SOIs, what we're attempting to identify common terms, that's another location. I mentioned that this morning. NHANES is potentially a very useful source of a large body of data of how people are referring to the things that they are consuming and how they are being characterized. Tremendous number of data cleaning problems, but it's an area where people have been working on those data cleaning problems, and I know that there's already some degree of association between the Agency and the researchers in that area. So, that's a potential source of information on commonly used terms.

MS. BARRETT: Good point. Let's not reinvent the wheel.

MR. PACKMAN: John Packman from DLA Piper. You asked about models. I think 130.10 is a great model. Talk about something horizontal that cuts across all the

different standards of identity. And it seems to me if it's feasible to come up with a regulation like 130.10, that manages to bring together things as diverse as nutrient content claims and all the different standards of identity, it would be possible to craft a regulation that would respect entities' First Amendment rights and that would ensure complete transparency to the consumer. If you carefully crafted it so as to ensure that if the name -- if a product name, if a statement of identity uses a standardized term, then it must transparently communicate, in addition, the ways that the product differs from the food described by the standard of identity.

MS. BARRETT: Please put that in your written comments, okay? Okay.

MS. CULP: Julie Culp, General Mills. So, I agree, and I think, again, the citizen petition from 2006 helped start that conversation around some of these categories that would make sense to introduce from a horizontal approach standpoint. I think a good reminder in the context of innovation is we've talked a bit about more, you know, frame-breaking innovation, like coconut milk versus other beverages, but the reality is innovation is pretty broad, right? So, that may mean a minor processing change that just enables manufacturers to be more efficient. It may mean a minor enzyme change that helps us decrease a nutrient level 10 milligrams, right? These are positive but small step-wise changes that all fall under this umbrella of innovation, from my perspective. So, I think the horizontal approaches, the category, the buckets of categories really does help address both. Some of them more frame-breaking innovation needs as well as these more minor flexibilities that encourage that overall.

MS. BARRETT: Thank you.

MR. VON FRIEDEBURG: We talk about vertical changes, what about focusing -- sorry, horizontal changes; what about focusing on vertical changes within a certain -- identity in a certain category? Because I have trouble figuring out the discussion, whether it applies to canned peas, for example, or to ketchup, or are we talking about plant-based, you know, meat or

cheese? So, could you clarify or is this something we can talk about?

MR. REESE: I think that's something we can consider as we're moving through this. If you took all as vertical, we wouldn't have the resources to do that, and kind of leads into the question 4, which this gentleman over here had alluded to about how do we make changes across categories of SOI to accommodate future innovation? He had mentioned what about using 130.10. Another thought is in that same vein, could we allow the use of all safe and suitable ingredients in a category, such as sweeteners, across all standards that call for a sweetening ingredient? Standards would not have to be revised as new, novel sweetening ingredients come onto the market. That's something to think about. You know, do we move it in the same way that 130.10? If we focus on vertical, I don't think we'd -- there are too many of them and --

MS. BARRETT: The resource issue is a big issue.

MR. WILDGEN: I just want to comment on the idea that I think the representative from the North American Meat Association -- I might have misunderstood this. If I understood correctly, I think it was sort of a suggestion to standardize the qualifying terms that are being added to standardized products. One, or a couple words of caution on that. We're talking about food innovation of the future, you know, it seems like it would be very burdensome on the FDA to have to regulate each qualifying term as they arise. We don't know -- you know, we know all these various types of noodles right now and all these new plant-based milks, we don't know what's coming next. So, we're going to have to do notice in comment or some other type of process every time there is a new innovation? And then, again, if you do go through that kind of process and end up getting it wrong and end up being unduly restrictive, you are once again opening yourself up to a First Amendment challenge.

And also to the question about health concerns and consumer confusion, what should the standard be there? And as the gentleman in the back said, there is a large body of case law that has arisen because of lack of

clarity and regulation, and that case law, at least when it comes to plant-based milks, has said very clearly that we should be using a reasonable consumer standard. What would be the reasonable consumer be expected to understand on this label, and if the reasonable consumer understands it, just go with that. So, I suggest maybe continuing on with the flexible approach that the FDA currently has, but once again just clarifying that approach.

MS. BARRETT: Thanks for your comment. Dan has already referenced question 4, so really at this point, if you have thoughts on any of the questions that we've raised or in the space of innovation and horizontal approaches generally, I will look for hands.

MR. MARRIOTT: Thank you. Robert Marriott again. With regard to variances from standard of identity under whatever structure or variance that might occur, it seems like it would be convenient in considering the transformation of current standards of identity to break down the standards of identity by different components of the identity, turning those into categories and then implicating the same labeling change for each subcategory. So, I'm going to use the proposal's examples that you have in the materials we all have.

One of these is referring specifically to ingredient substitution. I'm just taking that as an example. These different proposals could have different ones. The same variance labeling requirement could be the case for all ingredient substitutions that are considered appropriate under whatever the regime is. And that way at least the procedural burden aspect of this process is a little bit more straightforward, because you're not having to re-litigate the nature and structure of how that is being communicated to consumers in each case. That standard can be established once, and it can apply to all components of SOIs that are otherwise acceptable for all ingredient substitutions.

MS. BARRETT: Again, I want to encourage people to put these thoughts in your written comments and maybe build them out a little bit. You know, what would that look like, examples.

MS. GALLIMORE: Casey Gallimore with the Meat Institute. Just to kind of respond a little bit, I get the concern, I mean, any time you ask regulators to get involved, generally, I'm anti that, but -- just because, you know, there's red tape and it can restrict innovation. But when you already have a standard set and then the general rule or policy that exists is that if you use a qualifying term with that standard then you're free from complying with that standard. That's when the standard then becomes a barrier in the marketplace to those who don't use a qualifying term on it. So, and maybe that's a time when we evaluate whether a standard is necessary at all. So, I guess my point is more that if we're going to have a standard, either everyone should have to comply with it to some degree or no one should, so that we have a real competitive marketplace.

MS. BARRETT: I hear you. That's fairness. Okay. More thoughts? Okay, well, what we can do is, we took a lot of notes and, again, I want to thank Mabel for her excellent flipchart work. And, Dan, maybe we can talk about some of the themes that we heard and see if that sparks any further ideas, and we'll go from there. We have a little time left, so, Dan, I'm going to turn it to you.

MR. REESE: Yeah, just some of the themes that I was able to pull out of our discussion today, and please feel free to jump in if you see that I missed any or that are not fully captured.

Some that I saw were that we had undefined, there is confusion around nutritional inferiority, fermentation products, preventing consumer deception, innovation that allows a deviation from the standard so long as it is explained on the label, constraints for products within a standard. I think the last point was just made that, you know, fairness in using a standardized term; either you meet the standard or you don't. Challenges with First Amendment, free speech and commercial speech related to standards. The possibility of using a vehicle such as a 130.10-like regulation for a horizontal approach. Guidance on qualifying terms for standardized names. Meeting consumer expectations through thorough and transparent labeling. How products

differ from the standardized food. Increased consumer -- there will be increased consumer confusion if the understood terms that are currently out there were to be removed. Those are some of the themes that I noticed. Happy to hear any other comments.

MS. BARRETT: Anybody wants to elaborate on that, or if you feel like you said something and it hasn't been reflected either in the written note or what Dan said, but it was sort of an important point that maybe we didn't capture? Or just hearing it from Dan and you're, like, I want to add something to that.

MS. DERBES: Elizabeth Derbes from the Good Food Institute. Just a comment on the fairness point. Fairness sounds great; nobody's against fairness, but I'm not sure it makes sense to say that if there's a standard that some people have to comply with, everyone should have to comply with it when other manufacturers are not making the same product. So, I'm not sure that butter manufacturers are harmed by peanut butter manufacturers not having to comply with the standard for butter, or, you know, rye bread not complying with the standard for bread. You know, if consumers don't think that they're getting a meatball when they buy something that says meatless meatball on the package, it's just not evident to me why that standard should be applied, if consumers know that they are not buying the same product. And the whole point of qualifier is not to get out of using the standard, it's to describe a totally different product.

MS. BARRETT: Thank you. Thanks for your comments. Yes?

MR. HASS: To answer that, I think it's the other side that's the issue that's being mentioned. It's not -- it's not that, you know, a meatless meatball manufacturer can't make meatless meatballs, it's that the meatball manufacturer is constrained by the standard of identity. So, you know, taking life -- I can't call my product kefir because there's a standard of identity that says I have to call it something else. But someone who is not following -- someone who puts a qualifier in or doesn't. In our case they don't even put the qualifiers in. But, you know, to use coconut milk as the example, if I'm making milk, I have to follow the standard of

identity. I can't say milk, sort of. If it's dairy and I want to call it low fat milk, I've got to do what low fat milk says in the standard of identity. I don't have the option as a dairy manufacturer to say it's dairy, light dairy, and I'm going to go ahead and do this. Because I have dairy in there, I don't have that choice. I'm not making a -- I can't do that, and then when you see that, you can see that if you look at, you know, Dean Foods 1% milk is just like Organic Valley's 1% milk, I mean, if they were both organic, I guess. We know those two things are the same. Blue Diamond's almond milk is not the same as Silk's almond milk. They're totally different products with varying levels of different things, lots of different ingredients.

So, we tend to talk about the alternative products as though they're all the same, and I think that's really what we're getting back to here is that the people who have a standard of identity are being constrained to follow the standard of identity that they don't get to free out by throwing a qualifier in there. They don't have that option, and that's the fairness issue, not so much the innovators out there who can already do those things.

MS. BARRETT: Lots of hands up.

MS. DERBES: Just a very brief comment. That seems to boil down to a complaint that some people, some manufacturers have standards of identity and others don't based on the food that they're making. I mean, if it's purely a competitive concern, that I think is different than informing consumers as to what they're buying.

MR. WILDGEN: Yes, Gabriel Wildgen with Harvard Law School. I would second everything that Elizabeth from the Good Food Institute said, but regardless of where we come down on the fairness issue, the First Amendment does not care about what is fair in this regard, and so these arguments would never hold up in court. I just want to point that out.

MR. PEARSON: Justin Pearson from the Institute for Justice. I mean, it sounds more like your complaint -- to the gentleman in the back -- is about the standard of identity for your product. And the reason these standards of identities are allowed to exist

constitutionally is because they're tied to protecting the public. If the standard of identity that governs your product actually is tied to protecting the public, then so be it, and if it's not, then that's a problem with that standard of identity. But it doesn't make sense to say that because you have one standard of identity that protects the public for one type of product you should then force a different product that doesn't have those same problems, or concerns, to use a better word, to shoehorn it into that same regime. What matters is public understanding, public safety, and either that's being protected or it's not.

MS. BARRETT: Thank you. And, again, we came into the room realizing there are going to be different perspectives, and I do appreciate everybody having the dialogue and bringing out different points. It's been a good conversation.

MS. GALLIMORE: Casey Gallimore from the Meat Institute. Just to give a specific example to reiterate this gentleman's point over here. The term "burger" is a standard of identity, and for me to use the term "burger" when I'm making a ground beef product, I have to use ground beef. I have specifics on what types of beef can go into that ground beef, and I can't use much else besides just ground beef in order to call it a burger. If I add some kind of flavoring to it, I can't call it a blah-blah-blah-flavored burger; I have to call it a this type of flavored beef patty. I no longer can use that standard. So, that's kind of what we're talking about.

I think the alternative products are great for many reasons. We're pro alternative products at the Meat Institute; many of our members make them. But the difference is, you know, part of the reason that these standards of identity exist are for economic adulteration, and so burgers have that standard of identity so that, back in the old days, you know, things got added to burgers that made them not just ground beef anymore. And that's our concern, is that those types of stringent regulations, which are good, so that the consumer, when they order a burger they get a burger. But a veggie burger, you could add binders and emulsifiers and lots of things in there that we can't.

So, I mean, it won't be just protein that they're getting. You could add a bunch of bread in there just to up content without upping any protein. There's no rules against that for a veggie burger.

MS. BARRETT: Thank you.

MS. CAMPAGNA: Shannon Campagna with Van Scoyoc Associates. This has been a great conversation. My clients are primarily in the plant-based space, and I would just say I think we're starting to talk -- the audience is starting to talk to each other, but I want to kind of put it back to FDA that for us, that's why we're here, to really look at SOI and open them back up. Because I think there are limitations that the traditional foods are bound by that perhaps are not fair vis-a-vis the bare plant-based or other alternatives, and I think that's why it's really time to step back and take a fresh look at really modernizing and kind of looking at this, you know, taking a step back and thinking, okay, what is really fair and what's helpful, and do we really need to look at these economic adulteration issues that we had at the turn of the century.

And I would commend -- a lot of you probably know about the book *Poison Squad*, which is about Dr. Wiley. Super fascinating and it really kind of opens your eyes as to why the standards were created. But I think, as a couple of people have said, the economic adulteration issues and the risk is minimal, there are still concerns, clearly, and that's why FDA is here, and we appreciate their role. But I think that's why this meeting is so important, so I'm grateful that you're here and having this debate -- conversation.

MS. BARRETT: Great. Thank you. Other comments, thoughts? I think we're getting close to closing, but we have time for maybe one more. You guys are done?

Hey, I thought this was a really good conversation. I appreciate it. It was really refreshing to hear people share their views. And a lot of things were said that I hope you will capture in written comments. I hope if a perspective was shared that is not your own, that you do give it thought and maybe as you do your written comments, how you can address some of these

other concerns that have come up. Because that's the position that we're in, is trying to figure out that path forward. But you guys have been really helpful, and we're going to take a break and we're going to meet again in the large ballroom at 2:35 for our comments. Thank you.

(Whereupon, at 2:13 p.m., the breakout session was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, SAM VARIPAPA, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

SAM VARIPAPA
Notary Public in and for the
District of Columbia

CERTIFICATE OF TRANSCRIBER

I, SANDRA TELLER, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

SANDRA TELLER