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HORIZONTAL APPROACHES TO FOOD STANDARDS OF IDENTITY MODERNIZATION

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C O N T E N T S

P R O C E E D I N G S

SIMULTANEOUS BREAKOUT SESSIONS BLOCK #1

INDUSTRY INNOVATION

MS. BARRETT: So welcome, everybody. This is the breakout session on Innovation. I want to remind folks we are also being webcasted so welcome back to the webcast audience. We're going to walk through the questions that you all received. And, again, for those on the webcast they're available on our website.

Before we jump in, I want to introduce our Innovation team. Again, I'm Kari Barrett. I'm the Team Lead for our Public Engagement Communications and Public Engagement staff at CFSAN.

I have Dan Reese with me. You met Dan earlier. He's a Team Leader for the Product Evaluation Labeling team in our Office of Nutrition and Food Labeling at CFSAN.

And on the flipchart, we have Mabel Lee who's a Consumer Safety Officer, Office of Nutrition and Food Labeling at CFSAN. Want to thank her. She's going to be jotting down just a few of the key points we raise up today or the themes.

And then we also have Joan Rothenberg here who's regulatory counsel, Office of Regulations and Policy at CFSAN, to take a few more not overly extensive notes, but ones that then we can bring and feed into the wrap-up at the end of the day.

We also have a transcriber in the room. Where's our transcriber? She may be -- yes. Thank you very much. Yeah. Good to have the transcriber here too. As mentioned, historically we haven't always had one in the breakout sessions, so we're really pleased that we'll have a full record.

I also want to figure out who you all are today so I'm going to kind of run through some categories of who you might be and if you can raise your hand just so we can get a sense. But we're interested how many folks here are from industry today? If you'll raise your hand.

Okay. How about folks representing consumer or public health organizations? Okay. Got a couple.

Government officials? Okay.

Researchers? Researchers?

Okay. How about media? Any media with us right now? No.

Okay. Any other categories generally? Okay. All right. Well, thank you. It's always helpful to know who you're speaking with.

What I want to do is just give again a quick session overview. This is -- this particular breakout is focused on exploring the specific changes that the agency could make to existing Standards of identity across categories of standardized foods. And that's what we're talking about when we talk about horizontal changes to better facilitate industry innovation.

As mentioned from -- we harken back to our Nutrition Innovation Strategy that our goal is to modernize Standards of identity to allow manufacturers new flexibility to take advantage of advances in science, manufacturing, and technology while maintaining the basic nature, essential characteristics, and nutritional integrity of standardized foods.

In particular, we want to learn if and how SOI may impose barriers to industry innovation and what specific changes would help to remove these barriers.

So, I think I've noted at least three or four times you all have the questions that we're going to walk through. We did provide some of the proposals that we're received to date either through comments or conversations just for your consideration so you can feel free to speak to those.

During our conversation we want to hear your perspectives and questions on these proposals. And I do want to note when I say that, you know, Dan is a subject matter expert. He is here in his expertise, but we're really here to facilitate the conversation with you. So, we're really hopeful that you'll give your input.

If you have a question about how the agency might handle something, we'll probably feed it back to you and say if you were the agency how might you handle that, okay? Because it's really an opportunity for us to gather information from you and we don't often have that opportunity, so we really want to take advantage of it.

I do have a few ground rules I just wanted to cover. Again, if you can -- when you speak if you can

introduce yourself and you affiliation. We do have a microphone here and if we're comfortable maybe we can sort of pass it around or move it around. We'll see how that works. But when we start out we might just have people come up to the standing mic. Again, we do have the webcast audience and so I don't know how much we can run around the room.

You know, any idea and opinion is welcome, right? This is -- there are different perspectives in this room. That's great. That's how it should be. So please feel free to share. Please be respectful of each other. Please be as specific as you can. You know really feel free to dive down into your comment to give examples.

And we also ask if you could stay on topic. We do -- I'm getting a little feedback. Okay. We do have a parking lot if something comes up it's not on topic we'll place it there, we'll note it. But we really want to spend our time on innovation and horizontal standards and what that might mean or look like.

And with that, I think we're ready to jump in. So, what we're going to do is we are going to walk through each question. Dan and I are going to go back and forth. And we're going to give you guys a lot of time to share your thoughts and feel free also if somebody has a comment to pick up on that comment, to pick up on themes to help us capture the information as well as we can.

So, the first question -- and I am going to sit down. This is meant to be somewhat casual. If I need to run around a mic I'll do that, but we'll start out, again, with people coming up to the mic.

But the first question is really do Standards of identity post barriers to industry innovation? And if the answer is yes, then if you want to dive into what specific SOIs or categories of Standards of identity you're talking about and what are the barriers that you see.

So, do we have anyone who wants to sort of kick us off here with some thoughts on that? We've heard that people think there may be some barriers.

Yes, Michelle. Again, if you will introduce

yourself and your affiliation.

MS. SIMON: Michelle Simon from the Plant-Based Foods Association. So, our industry's a bit different in that there's so much innovation going on that there aren't current definitions that fit most of the categories that our members make which are alternatives to conventional meat and dairy products.

So, I guess my question is and the challenge has been where there are Standards of identity that hinder innovation in kind of a neighboring field, if you will, is there any flexibility there? How is the agency thinking about, you know, where our new industry is sort of overlapping with in this case, say, you know, the conventional dairy industry? What do we do about that?

And it's coming up somewhat at the federal level, but even at the state level where there are states that have definitions, for example, of dairy products and our members aren't able to use certain words even with clear qualifiers, right.

So that's kind of where we're coming from so from an innovation standpoint, you know, there's a real concern that if a start-up wants to make, you know, a plant-based yogurt, for example, but they can't use the word "yogurt," that means they cannot communicate to a consumer the expectation of that product. And, again, with clear qualifiers. No one's trying to fool anyone here.

So that's the concern that I hear from our members that if we can't use words that consumers understand, then that's going to stifle innovation because, you know, it's very expensive obviously to get a product to market and it's a real barrier to not be able to clearly communicate.

MS. BARRETT: Thank you. That's good points, yes.

MS. FRYE: Hi. Cary Frye, International Dairy Foods and Association. I wanted to talk a little bit about ingredient and ingredient technologies and sort of highlight something that we brought to the agency before, but just in general because other people might have similar.

It has to do with as ingredient technology has

evolved particularly the area of ultrafiltration. So, you can take milk and filter it through the very specific filters and come out with products that are higher in protein, lower in sugar, higher in minerals.

So, they could be beverages or they could be an ingredient for cheese at certainly an advantage for nutrition and also an advantage for making a high-quality cheese product that is similar nutritionally and compositionally to the standard.

And so, we have seen this and I know the agency has addressed it particularly with ultra-filtered milks and cheeses allowing some regulatory discretion. But it is something that the dairy industry realizes that the technology keeps moving faster.

It's moving into microfiltration that allows more purity in a stream way that could be used for infant formula and also higher levels of protein for cheese. We know that this technology is used around the world. And those cheeses are very high quality and allowed under Codex standards.

So, I just wanted to bring that forward as an example of where there is a barrier to ingredient technology. Thank you.

MS. BARRETT: Thank you, Cary, for that example.

MR. TANNER: Hi. Ron Tanner with the Specialty Food Association. I don't know if this is a barrier or not because I don't think people are following the Standards of identity, but I'm going to men- -- and let me say I'm neither a food scientist nor a lawyer so please give me some leeway in my comments here.

But we have many members of our association that make various types of water. Water is one of the faster growing categories in specialty food. And you've got water with blueberries in it, you've got a water with acai, you have water with vitamins in it. So you have all these different additive -- you know, natural additives I guess we'd call them, but all these different things that are put in the water to make them more healthful and to encourage people to be drinking the water instead of drinking sugary sodas.

And from my reading of the standards none of

these products can -- should legally be called water, you know. I think they all do call themselves water, but I just think some of these rules are really -- if people were following the rules they would be really affecting the innovation in these products. And by not following the rules they're not in compliance so that's not a good thing.

But we see that in different categories. We see it in fruit butters, we see it some in pastas and different things like that. So, I think just some of the rules need to be either eliminated, modified, or made less -- you know, less difficult.

MS. BARRETT: Thank you. Thank you for highlighting some constraints in that regard. Other thoughts, experiences where there have been barriers because of the Standards of identity?

MS. MILLER: Good morning. I'm Debra Miller from the National Confectioner's Association. It's nice to have a person with a peanut butter cup last name hearing our comments. Probably the first time you got that, right?

Just in terms of Standards of identity for the confectioner sector, chocolate is really the number one place where we face issues with standards and there are a number. And my comments later today will outline those.

But some of the barriers that we mainly face in terms of improving the nutrition profile of chocolates is alternatives to nutritive sweeteners. FDA has recently, you know, put forth guidance on allulose and the calorie declaration for allulose and where it falls in the carbohydrate declaration. But is it a nutritive sweetener? Is it -- you know, can we get some clarity on that?

Also there are some fibers and some proteins that can also be used in chocolate products that can take up the space for some -- for sucrose and other standard sweeteners and that would allow for an improvement in the nutritional profile, but currently would not be allowed to be called chocolate under the standards.

MS. BARRETT: Great. Another good example of barrier -- potential barriers. Yes. Come on up.

MR. ARCHER: I'm Patrick Archer. I represent

the U.S. Peanut Industry with the American Peanut Council. And as has been pointed out in the case of peanut butter -- and I think it's number one on your proposal list here -- we have a problem with flexibility in using more up to date and more modern stabilizers. It's a very short list.

And we would certainly -- there's certainly interest in our industry in having some flexibility in the type of stabilizer that's used in peanut butter so it can still be called peanut butter. If you don't use one of the short lists of current stabilizers that are listed then you have to call it peanut spread. And we find that confusing to the consumer.

MS. BARRETT: Right. Thank you for bringing up that example. Other areas of barriers? Yes. Thank you.

MS. WILKIN: Hi. I'm Edith Wilkin. I'm with Leprino Foods. And one of the comments I want to make is the agency needs to take a look at the really strict standards for formulating certain products that does not allow for innovation especially in light of the current -- the current atmosphere where we have to be really mindful of resource use specific to globalization and sustainability.

I think there needs to be some flexibility to allow some of these alternate methods for making certain foods that does not impede innovation and does not unnecessarily put the U.S. at a disadvantage when it comes to competing on the export market.

MS. BARRETT: Edith, is there a particular example of a food or product that you'd want to highlight?

MS. WILKIN: Well, to piggyback a little bit on Cary's comments specifically how you make cheeses, so that would be one example. But there's several other foods that have very strict how to make.

MS. BARRETT: Great. Thank you for coming up. Other thoughts around barriers?

MR. ZUEHLKE: Jesse Zuehlke from Prime Legal Consultants and Johns Hopkins. And just one -- I guess one thought to add. Specific example would be canned mushrooms today. Not allowed to add seasonings to them. That frequently happens and so as industry we just add a

qualifier? We'd call it canned mushrooms with seasoning or something along those lines.

And I think that's a common theme in a lot of standardized foods is adding qualifiers. So, a consideration that would be helpful to industry would be a framework within the regulation for how qualifiers to additions or forms or flavors could fall within a standard even if it, you know, today deviated from the standard then.

MS. BARRETT: Great. Thank you. Okay. Yeah, Sarah? Again, if you'll say your full name and affiliation.

MS. SORCSCHER: Sarah Sorscher, Center for Science and the Public Interests. This is more of a question for the audience actually but, you know, given that there's a lot of flexibility now around being able to create an innovative product and make a common or usual name for that product that's distinct from the standardized name, non-misleading to consumers how -- what specifically is the need for being able to innovate and then also take advantage of the standardized name? What challenges are people running into in that space? That's kind of a question that we've had in considering this.

MS. BARRETT: Yeah. Thank you for raising that. Does anyone want to speak to that? We can also as we move through some of the questions address that too. But I think, you know, indicating there is some flexibility, but then you -- you know, you can't use the standardized name and kind of where you might fall out. Any suggestions around that?

Okay. All right. So, we're going to move onto the next question. I'm going to turn this over to Dan. And that has a number of parts to it. I think he's going to walk through each part. So, Dan?

MR. REESE: Thank you. So, this has four parts. I'll just take each part as we go through it. We are interested in exploring changes that could be made across categories of standardized foods to better promote industry innovation.

Please share your ideas for specific changes that would help FDA achieve its innovation-related goals

by answering the following questions:

So, first is what change or changes could FDA make to existing SOI regulations to better promote industry innovation?

For example, as we discussed earlier in some of the presentations allowing for the use of salt substitutes in Standards of identity which currently only allow for sodium chloride.

So, what changes could we make to existing SOI regulations?

MS. BARRETT: So, if you woke up tomorrow and you could have your wish, what would it be?

MS. KATES: Hello. I'm April Kates. I used to be Dan's supervisor many years ago and now I'm retired and I'm consulting with EAS. So, I will say that.

And the one thing that comes up that I see now from companies that come to a consultant and ask for help on snarling regulatory issues is that if you look across all the standards, standards such as the bottled water standard are written with very specific quality characteristics in it.

But there are other standards such as maybe the cheese standard that are written more with recipe-based. Some of this difference is because of the age at which the standards were produced, you know, when FDA wrote those Standards of identity.

But I think as FDA looks at trying to get an approach to how to attack these standards and modernize them -- and I know Dan probably already knows this -- is to look at how you can almost standardize the standards.

So, is a standard going to be based on an ingredient basis or is a standard going to be a quality basis? Are you going to have microbiological standards or, you know, mineral content or nutritional basis or is it going to be based on the ingredients?

And I think when you look at it that way it may make it a little easier to approach. So that's all I wanted to say.

MR. REESE: Thank you. Seeing no other -- oh, please.

MS. MILLER: Debra from the Confectioner's. Just an example of -- in terms of sweeteners, when you

use a nutritive sweetener like sucrose in a solid food product it's a little different than exchanging it out in a liquid form because you have to account for the bulking component of sucrose. It takes up a lot of space in a product so it doesn't just contribute to sweetness.

So, in trying to produce sugar in any kind of solid product like chocolate or another standardized product you have to account also for that bulk, for that mass that's removed. So, adding other ingredients like I'd mentioned before -- proteins and fibers -- can actually add that mass without -- while keeping the sugar lower if other sweeteners and other technologies as they become available are used in these products.

But you do have to account for other things which is why sweeteners alone in a one-for-one substitution sometimes isn't quite enough. So, in terms of really creating the product that people like it's a little broader than just a one-for-one for sweetener to sweetener.

MR. REESE: Any other comments on that topic? The next one kind of was following the same line and we kind of covered that. Which standardized food or food categories would be impacted by the change?

We mentioned a few of those examples in sweeteners and so forth. So, I'll move to Part C. How would the change better promote industry innovation?

And I guess I'll kind of combine that with D because they all kind of go together. What are appropriate limits to this flexibility to ensure the standardized foods continue to meet consumer expectations?

For example, 21 CFR 130.10 allows modifications to a standardized food if a nutrition claim is being made. Are there any other appropriate limits for changes that do not impact nutrition, but are for functional purposes?

MS. BOOREN: Hi. Betsy Booren, GMA. And I apologize, I was out for the first part of this so if this has been said I'll say it again. I think as I look at particularly this question number two and the subparts, I think the challenge that FDA has, and I think industry will have is we're being very specific on

categories in foods that'll be impacted now.

Our encouragement would be making sure we have the appropriate regulatory framework that allows this system to expand and grow as technology and consumer demands expand and grow. And that's part of the reason I was excited to hear about the reopening of the rule, but the challenges that I'm having answering some of these questions is I'm trying to think what will the industry -- the challenges have for industry in 5 years, 10 years, 20 years knowing that this is a long process and we've got to think that way?

My encouragement would be as we look at this it will probably be all categories at some point. So, what is the right framework, guiderails that we need to have in place to prevent that barriers is really where I think the focus should be. And we've -- GMA's provided some of that.

But I think that's part of my reason for not coming up and answering all these questions is I'm trying to think more holistically at that right framework for what it's worth.

MS. BARRETT: Do you have further thoughts on that framework?

MS. BOOREN: Of course.

MS. BARRETT: I mean, I know -- yeah.

MS. BOOREN: Yeah. Of course I do.

MS. BARRETT: Share some of what you've said in the past.

MS. BOOREN: And -- well, and I don't have my other comments so I would -- I'd like to put a pin in that and follow up because I think GMA's been very vocal and have been working with the industry on the petition and so forth.

But I think this broad approach is appropriate and I know many of the other food trade organizations and consumer groups and other stakeholders have very perhaps product specific. Our focus will be looking at that broader framework.

And so, we'll be in touch with more thoughts, but that is the reason why I'm not stepping up on every question is because I am trying to think more holistically on this process.

MS. BARRETT: No. Thank you for coming, though. And certainly, I think we all acknowledge with the speed of innovation it'd be very -- it's very challenging to keep up with that. So how do we put something in place that can keep up?

Cary, did you want to introduce yourself and affiliation?

MS. FRYE: Cary Frye, International Dairy Foods Association. I just want to build upon that. I started earlier with the ingredient technology of ultrafiltration. And building on what Betsy said, we very much endorse a holistic approach to looking at standards modernization not by each standard or each ingredient should permitted here or there, but allowing this broad, horizontal approach where there could be flexibility in ingredients to allow for new technologies like ultra-filtered milk.

Because ultra-filtered milk can be a superior drinking beverage, it could be allowed in yogurt. It is allowed, but only at certain levels. It could be used in ice cream rather than right now the standards allow for caseins or casein needs because they didn't know about ultra-filtered milk as well as cheese.

So, we need that holistic approach from the dairy perspective, but all foods. We want that as a superior ingredient maybe in baking or cookies or pudding. So, having that approach looking broadly at allowing for flexibilities in ingredient technologies as long as there are some provisions for the final product being something the consumer would recognize and also maybe it's compositional.

We want to have nutritional flexibility, but there needs to be somehow the consumer would recognize the product but still allow for the flexibility. And I think the approach of horizontal standards certainly we support it, but just giving this example of ingredient technology of how it can go across standards and then across foods. Thank you.

MR. REESE: Any other comments on question number two?

MS. SORSCHER: Yeah. I have specifically some -- this is Sarah Sorscher from CSPI again. I

specifically have some comments on Part D. You know, I think in prior efforts to enhance flexibility with Standards of identity have attempted to put in place certain guardrails to make sure that consumer expectations were met, there wasn't a food safety risk.

And, you know, one of those was this requirement that ingredients be safe and suitable. And I think when that rule was developed in the late 70s there was a presumption that FDA would actually be doing a safety -- a premarket safety review for new additives and that's built into the safe and suitable definition.

And what we've seen since the late 90s is that increasing FDA is delegating that role to industry through grass proceedings which can be conducted in secret. And I think as consumers we have a lot of concerns about that being an adequate safeguard to ensure that new additives being added to standardized foods are going to be safe and reviewed.

Another point, you know, what I said earlier is that a lot of innovation is allowed so under a new name for the product. And to the extent that companies are seeking to use a standardized name they really want to tap into and take advantage of consumer expectations around that food and what it is. So, it's important that those expectations be met in some way.

I think in the past the agency had rules around not changing any ingredients that were mandatory under the standard and not adding ingredients that were prohibited under the standard. And I think that that's a reasonable approach, but I'm not sure it really cuts to the core of what consumers expect about food in each individual case. I think in some cases process plays a role.

And so, you know, that's something I think the agency should probably consider, but may not be sufficient. Also, the agency had requirements around declaring the percent of a characterizing ingredient. And I think those -- that's good in theory, but in practice we haven't seen a lot of those percentages used in products and so that hasn't been great for protecting consumer expectations in that space.

Finally, I think while we think about broad

overarching principles, it is important to recognize that some level of case-by-case review is still needed. Looking, for example, at, you know, this last proposal of using alternative manufacturing processes to produce standardized foods thinking about cheese making, a new technology there.

You know, right now a lot of the Standards of identity for cheese have minimum aging periods. And I think, you know, it's important to take another look at those and see if they're really needed. But one of the things those do actually is raw cheese is allowed for the cheeses that meet those Standards of identity and the aging period is the primary, you know, food safety measure to prevent that from introducing pathogens.

And if you're thinking about smaller companies, companies that may not be subject to preventative controls rules, you have to think about what role that Standard of Identity actually plays for food safety for those products.

And so, you know, just loosening things up across the board thinking about the future and flexibility may not be enough to ensure protection on that case-by-case basis.

MR. REESE: Thank you.

MS. BARRETT: Yeah, no. Thank you. And I think you raised a good point too that, you know, it doesn't necessarily have to be one or the other that we completely go to horizontal categories, you know, versus specific standards. That there may need to be both depending on the criteria that you're looking at. And certainly food safety is critical.

So other thoughts? I think you raised a lot of good points. I'd really welcome anyone in the audience to speak to some of that or maybe that sparks some new ideas for you.

All right. Well, we'll go -- we'll at least bring up the next question which is are there existing models or example out there that we can look to? Is somebody -- is there another government, another agency/organization who is taking steps in a direction that you would find encouraging and would recommend that we take a deeper look at?

So, we'll welcome some thoughts in that regard if anyone wants to come up. If it's also helpful to run the mic around, I'm looking at the back, I'm happy to do that too. I know sometimes people -- it's a little uncomfortable to walk around so we'll see how that goes. But welcome your thoughts.

MS. SIMON: I like getting up and moving so. Well, thank you for this question. I'm really excited to share what we've been doing at the Plant-Based Foods Association.

As I said, you know, our categories are so innovative there aren't definitions. And so we had to think about, well, what does it look like for our industry? And what we realized was, you know, our members are using essentially common and usual names.

So, like almond milk, right? It's been around for a long time. Everyone understands what it means. And so what we're -- but what we recognize is that there is a lack of consistency within some of these categories. And so what we want to do is help our industry members with how to come up with a more consistent approach.

Not to necessarily, you know, get a legal definition of almond milk, but to guide the industry with if you're going to use a word like that here's what we think it should look like, right, to allow for the industry to come together and create a voluntary standard around a word like almond milk that we recommend our industry members follow.

So, in 2017 we formed a standards committee and we put heads together and said, okay, you know, what do we need to do to make this happen? And we did a consumer survey. And I'm happy to say we got FDA's input on that instrument and then, you know, put it in the field.

So, we got feedback on, you know, what kind of qualifiers to consumers understand? Is it dairy free, non-dairy, plant-based, you know? So, we tested all these different phrases to help guide this process so that we weren't just, you know, making it up or, you know, arguing amongst ourselves. We actually got some data behind the proper qualifiers to use.

And then we decided to also create some, you know, definition around, well, if you're going to say

it's almond milk it's got to have some minimum amount, right, so to have meaning to using a word like that. And, again, to not get into too much of the weeds as some of the standards do around, you know, X amount of fat or protein and all that, but rather just say it's got to have some minimal level of content of the ingredient that you're calling it.

So that's kind of the approach we took and we put out the results last year. I shared that with FDA and say, hey, you know, this is what we think is the right approach. Industry members coming together guided by consumer survey and consultation with FDA and we think we got a pretty good result out of that first go around.

And now we've moved on from almond milk -- sorry, from the milk category in general to other subcategories in our industry. So right now we're working on yogurt which we thought would, you know, be an easy add on -- follow onto milk and now we're also looking at meat alternatives.

Little trickier. Lots of, you know, more complicated factors there. But, again, we also put a consumer survey in the field to help us understand what the qualifying phrases are that resonate with consumers. And so we're planning to come out with both of those by the end of this year.

And so, you know, we think this is, again, good approach, a parallel path to, you know, creating what could be innovative, you know, damaging definitions by government bodies. We think, you know, we figured out how to kind of come together.

And we're seeing some actually at the state level -- for better or worse some states even have taken up this idea of using pop-up qualifiers to allow for using meat terminology. And we can talk more about that.

But so, the point is this is an industry-led voluntary initiative that also we can revisit year to year. And we've also -- one more thing and I'll stop. We tied it to our certification which is really an exciting development. So, we have a plant-based certified seal that is, you know, a voluntary third-party verified seal.

And so, after consultation with FDA we decided

to take that a step further. So, anyone who gets that certified plant-based seal has to go through -- has to adhere to all voluntary standards. So if an almond milk company wants to get plant-based certified they have -- they are then looked at for our voluntary standard to make sure they adhere to that.

So that's just an extra, you know, confidence builder for the consumer when they see that that they understand that they're following a certain standard. So that's our approach and, you know, we're obviously able to review it year after year. We don't have to go through a whole rulemaking process. It's a little more flexible in how we can make changes and updates to it.

MS. BARRETT: Yeah. Well, thank you. Thank you for sharing that. And I'm sure it gave you a greater and deeper appreciation of what that process is like and how long it takes and how challenging it can be.

But you raised some really good points about can voluntary industry consensus standards coupled perhaps with some mandatory elements like consumer studies or certification -- is there a role for that in this new process going forward and what that might afford and what concerns there might be around that.

So, welcome any thoughts in that regard as potential models or variations of models. Again, also if there are other government or global bodies that are doing work that you would recommend we look closely at. Welcome any thoughts in that regard at this time.

All right. So, you can maybe give that one more thought and I'll turn back to Dan for the fourth question that we have.

MR. REESE: So how can we make changes across categories of standards that would accommodate future industry innovation? And, for example, production methods or development of new ingredients to avoid the need for frequent Standards of identity revision.

Welcome your comments on this.

MS. BOOREN: Betsy Booren, GMA. I think part of this gets to hopefully what we'll see in the guiding principles. I think getting some clarity around what the guardrails are of what FDA expects may qualify or not qualify for a change in identity will help across there.

I think flexibility of what that innovation could look like could also help, but I think providing some of those guiderails will help with this. I think whatever framework will need to be will be one that will need to grow for 10, 15, 20 years.

That said, I appreciated the comments about consumer expectations. The speed of what consumers demand for the consumer package good industry is happening at a rate that is unprecedented. It's the speed of sending a tweet.

So, having the capability to have our federal agencies be able to pivot very quickly and be nimble is going to be critical moving forward. FDA has the legitimacy of a regulatory agency and so the inability of having a system that's able to grow with innovation -- but we will run into issues, products, ingredients that may need FDA to take immediate action, there should also be a framework for that.

Otherwise, products don't go to market in an efficient way and we start seeing things happen at a state-by-state level where consumers expect -- we anticipate consumers expect that FDA's already regulating it. And so, then there's potentially unsafe product out there.

So, it -- to me it's a combination of both which is, I recognize, not easy. But it's one that I think should be considered.

MS. BARRETT: Thank you. Those are great points. And, you know, again, we've touched on the consumer demand, the speed at which innovation is occurring, but still have this underlying need and responsibility to ensure appropriate consumer protection and interest and equally be able to, you know, pivot there quickly and, you know, hopefully build in those safeguards.

So welcome further thoughts on sort of this idea of how do we keep up and how do we have something that will be a framework that we can move into over the next 10, 15, 20 years? Is that possible? What are people thinking?

MS. MILLER: So, Debra Miller from Confectioner's. I don't envy you this task, very

complicated. But one that perhaps cuts across a number of standards is the -- for standards that have limited optional ingredients.

And I just bring back to the example that I mentioned earlier when if another -- let's just use sweeteners as an example -- may be allowed to understand the technical limitations of those sweeteners or other emulsifiers, stabilizers, what have you if they're used in place of something that is currently allowed there may be some other additional things that may need to be allowed to really make -- to allow for the same functionality.

So, taking up the bulk for sucrose or, you know, a nutritive carbohydrate sweetener just thinking about the full spectrum of what those changes means. Because if you make then in a vacuum those other changes won't -- will still create the barrier if we don't have the flexibility to, say, add bulk if we're using a different type of sweetener.

MS. BARRETT: Thank you. And I know many of you are representing global interests. It's come up before are there concerns, barriers, opportunities if we look globally? Any thoughts there?

So, we have a few minutes. We are going to talk about some of the themes that we've heard and in reviewing those might spark other thoughts. But before we do that I just want to sort of an open mike on this topic of innovation if there was something on your mind that didn't neatly fit into the questions, maybe it's prompted by the examples that we gave we'd welcome that.

MR. TANNER: Ron from Specialty Food. I mean, this is a very broad question and I know earlier I said something about eliminating standards. But when you look through the list here, I mean, it sounds like you're walking through a grocery store in 1960.

And today, you know, there's kimchi, there's kombucha, there's salsa, there's guacamole, there's granola, you know, there's just so many other products which are out there. So, my question -- this might be for Daniel with the peanut butter cup last name -- is how does that change as foods change? You know, should we have kimchi instead of chop suey, you know? How do these

things develop?

And I'm not -- you know, I'm not saying we should have more, but I'm just saying how is your thinking -- as the foods that people are buying are changing how is the FDA thinking changing?

MS. BARRETT: I mean, I think the fact that we're here is we're struggling in the same way, you know, that we have a certain framework that as you saw as we walked through the history does reflect sort of the past and not necessarily the future or even the present as well as it might.

So, what do we need? I mean, I think we said earlier what we have today isn't going to be sufficient going forward so there is going to need to be some change in this. And where do they make those changes whether it's horizontal standards, reducing the standards, having some hybrid approaches?

And, again, always being mindful that we are a public health agency and, you know protecting the public is our top interest. So along with, you know, allowing for innovation for healthier foods.

And so, any other thoughts come up? Yes?

UNKNOWN FEMALE: So just thinking very broadly about future ingredients and flexibility and we've seen a lot of movement in the hemp area since the 2018 farm bill. And certainly I know your agency is actively looking at a regulatory framework for CBD and other cannabis.

But, I mean, you know, it seems like we need to think about novel ingredients that are not in the food supply right now that may be in the future. CBD could be an example right now. But thinking about how those fit into this flexible approach.

MS. BARRETT: Yeah. Thank you. I was waiting for someone to mention CBD. It just wouldn't be an FDA outing without that coming up. Certainly it's a really good point but, yes, thank you for raising that.

Other comments?

UNKNOWN MALE: Just comments like as this gentleman said in the grocery channels you see a lot of products -- a lot of new products, categories coming up, you know. As industry -- a part of industry we're not --

we're not discouraged by Standard of Identity by innovating more products. It's not going to stop like a barrier to stop the industry to keep innovating to satisfy the customers/consumers' needs and expectations.

So, it's kind of a barrier, but it's not a barrier to innovate products to fit the marketplace. So at the end of the day, you know, as the food industry we want to make sure that we do it right for the industry, but also, you know, to make sure that the consumer not getting confused by all these new products. It is a very complex situation and happy to help.

MS. BARRETT: Yeah, thank you.

MS. HERON: Julian Heron -- excuse me, Julian Heron, Tuttle, Taylor and Heron. Just sort of a general comment as you're considering how to proceed out into the future two things to clearly keep in mind.

One, the ultimate regulator is the consumer because they're simply not going to buy it if they don't like it. And secondly, the advantage that everybody has now especially your agency is the fact that information flows freely to everybody that didn't exist just a few years ago. So, you can be certain of the fact that whatever it's believed is necessary to do reaches everybody instantly.

And the other thing very closely related to this, but not a Standard of Identity is simple labeling. The fact that the labels today contain so much more information than they did yesterday is a clear way to identify products -- new ones and old ones -- as to what it is and what's in it without the rigidity of a specific Standard of Identity.

You've got far more flexibility and immediate impact just through labeling.

MS. BARRETT: Okay. Thank you. And I'm going to come move this mike around -- I really like that -- to give some opportunity. But I think you make a great point that that's not our only tool and it's not the only tool for consumers as well.

Yes, Sarah?

MS. SORSCHER: So, I was going to save this comment for one of the other sessions, but since we're talking about labeling it -- so we do have a lot of tools

now, but they're limited in some ways. And one of them is declaring high-quality ingredients or public -- ingredients that are desirable for public health reasons.

So you can get sort of the rough predominance of ingredients from the food label and you can get key nutrition information from the food label, but if you're looking, for example, to make sure that you're getting half your grains whole with a product it's very difficult to tell from the existing label.

We have experts who struggle with different products to estimate the percent whole grains. And I think, you know, I mentioned before that the characterizing ingredient requirement was sort of meant to deal with some of that. And I think it's not something that's really been used. It's almost kind of voluntary whether somebody declares the percent whole grain. People tend to do it when it's 100 percent whole grain, but not 49 percent or 80 percent so I think that there is still a role for standards in that respect.

And then another aspect of this is that, you know, consumers especially with vitamins and sort of enriched products may struggle to really create that market signal that's targeted towards public health priorities.

And, you know, there's a Standard of Identity for enriched flour that includes folic acid. And FDA recently in 2016 allowed for makers of corn masa flour to enrich with folic acid as well, but no major manufacturer has taken them up on that offer.

And the primary population that consumes corn masa is the Latino population and they have the highest rate of neural tube defects. So, they are most in need of that supplementation, but somehow the market is not solving that problem.

So, having a mandatory standard for enriched flour that includes the vitamins that FDA and public health community has identified is important for the population can offer real value in that space as well.

MS. BARRETT: Other comments? I'm happy to pass it down. Anyone down here? Yeah?

MS. JUSTO: Andrea Justo, Mondelez International. Specifically for the chocolate and maybe

this fit in one of the questions but, you know, as a global company sometimes we're looking to expand products globally in the U.S. And I think there are some standard differences of what's allowed in, like, European chocolate such as whey or maybe cocoa butter alternatives which we don't allow in the U.S.

So, I think as you're looking at the standards maybe considering, you know, looking at keeping that in mind.

MS. BARRETT: Thank you. Good points. I'm going to look up in this section. Does anybody have a comment or something that they want to add? No? Okay.

All right. Turning this way. Can I pass it down, some thoughts? Raise your hand if you want me to pass it to you at this point. Yeah.

UNKNOWN MALE: Actually I have a question and it was addressed somewhat this morning, but maybe you could give us a little more insight into the general timeline of when some of this innovation is going to possibly be allowed versus the time that's required currently to have a petition reviewed for an SOI change.

MS. BARRETT: Yeah. I don't know that I have anything more to add to what Doug I think spoke on this morning. Timelines, as you know, are really challenging and we don't always control those as well. But I think, you know, we are recognizing the speed of which things are occurring and trying to be as responsible as we can as fast as we can. But there are lots of challenges as we've noted today.

Yeah. Over here.

MS. MCENROE: So, Diane McEnroe from Sidley Austin. Maybe just putting a placeholder on process. So I'm not getting specifics here, but if our options right now are TMPs or Citizen Petitions and they clog up the works if there's some guidance we can get out to think about some other way of looking at some of these more minor changes to a standard and whether language goes into the Standards of identity that allow for safer and suitable for ingredient issues or functional filtration processing issues.

And then you could think about it more nimbly through some other process, some guidance on how to do it

where they -- something was brought to the agency to support the modification but showing that it still has the essential characteristics of the standardized term. A thought.

MS. BARRETT: Yeah, great. Good. No. Appreciate giving us your thoughts in that regard. Are there other comments? Yeah. Yeah. Did you have something?

MS. SZYBIST: Not a comment, a question. Maybe I missed the answer. Maybe it was --

MS. BARRETT: Why don't I hand you the mike? We do have someone transcribing so if you'll say your name --

MS. SZYBIST: Okay.

MS. BARRETT: -- and who you're with.

MS. SZYBIST: I am Lynn Szybist and I'm with CFSAN's Food and Cosmetic Information Center. And one of the questions that I didn't hear the answer to this morning and I might be asked to answer the question soon after this meeting is when will the comments be opened for the 2005 rule and how long will they remain open?

MS. BARRETT: I don't know if we --

MS. SZYBIST: Was that --

MS. BARRETT: -- have that yet. I know --

MS. SZYBIST: Okay.

MS. BARRETT: -- it's been a process for Doug earlier said we're working towards that, but I don't know that there's exact dates yet that --

MS. SZYBIST: I didn't miss it?

MS. BARRETT: No.

MS. SZYBIST: Okay.

MS. BARRETT: Other thoughts? All right. Let's take a look at some of what we've captured and kind of share that with you back and then we'll see if there's some additional thoughts that come to mind once you sort of can collectively see this.

I'm going to turn over -- this over to Dan. And, Mabel, I just want to thank you for putting this up here for our benefit. Dan?

MR. REESE: Thanks. So some of the themes I noted during our discussion included flexibility, allowing for U.S. products to not be disadvantaged when

they're exported, qualifiers to a standardized name, regulatory framework in a holistic approach that allows for technology but also that the consumer will recognize, ability to react to consumer expectations.

Do you all have other themes or other things that you've taken from this -- from our discussion today? I'm happy to hear any of your thoughts.

MS. BARRETT: Are you just hungry? No. Honestly, I think it's been very helpful hearing your thoughts this morning. You can see we did take a lot of notes. We will have the transcript that will be available.

We do want to encourage everybody certainly to submit your written comments by the November 12th date. We can wrap up in a minute if you'd like, but I do want to just take one last look. If there's anything anyone wants to add please raise your hand.

All right. Well, listen. We're going to break a little early. What you're going to do is you're going to obviously go have some lunch. As mentioned, there is the buffet being offered here at the hotel if that's something you're interested in.

We will start -- when you come back from lunch you're going to go directly into the afternoon session breakouts so please refer to your agenda for that. They are going to start promptly at 1:00 p.m. And we look forward to seeing you this afternoon. So thanks, everybody.