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

HORIZONTAL APPROACHES TO FOOD STANDARDS OF IDENTITY MODERNIZATION

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P R O C E E D I N G S

MS. BARRETT: So, again, I just want to say good morning. We're all here today. We're going to focus -- our public meeting today is on Horizontal Approaches to Food Standards of identity which we call SOI Modernization.

My name is Kari Barrett and I'm going to be moderating today's public meeting. I'm within FDA within our Center for Food Safety and Applied Nutrition and part of the Communications and Public Engagement Team.

And I know that there is a great deal of interest in the issues that we're going to discuss today. I know we kicked off some of this last year when we had our nutrition innovation strategy public meeting. We've also spent a lot of time in the last year meeting with a number of groups on this topic and I'm really pleased to see the turnout today both in the room and I know we have quite a large number of people webcasting in today so I want to acknowledge that.

There is a special group out there that I want to say hi to this morning. They are potentially our future public policymakers. We have a group of Cornell University students who as part of an assignment are tuning in today. This is for a course on Federal Regulation on Food and Agriculture. And like most of you they also will be submitting public comment so we really welcome that and want to greet them today and thank you for tuning in.

Before we jump into the agenda there's always the housekeeping so I'm going to try to move through that fairly quickly. Just as I've already noted we are webcasting today all of the sessions that take place in this room. That includes the breakout sessions that will occur here.

And there will also be a transcript for all the parts of the meeting which is very nice. Because in the past we've had breakouts where we've provided a summary but we haven't had that transcribed. So today there will be transcripts for all the plenary sessions as well as all the breakout sessions.

We also are going to cover some of the key points raised today in our wrap-up session at the end of

the day so we hope that all of you will stick around for that. I also want to just reference the folder that all of you should have received. If you don't have it, they are available at the registration desk and it has a lot of helpful reference information in it. It includes the full agenda, all the biographies.

Importantly too it has the questions that we're going to be discussing in the breakout sessions and some background around that. So if you haven't had a chance -- it's also posted on our website for those of you who are webcasting in. If you haven't had a chance to look at that, I hope that you will glance at it, maybe spend some time with it at the break. Because, again, for our breakouts that's really our guide.

I also want to mention if there are media or press here if you haven't had a chance to check in if you'll do so. Jen Dooren, I see you. Jen, if you just want to raise your hand. Jen is the point of contact for any media or press here today. We also have Nathan Arnold who is also in the back raising his hand so thank you both.

For public comments, as all of you are aware at the end of the day we have time set aside for those who have registered in advance to give public comment. We have a fairly lengthy list and I know there's already been some modifications to that.

So if you can check in -- Juanita, if I can have you also raise your hand. If you can check in with Juanita at the break or lunch if you're giving public comment this afternoon just to confirm your intention and also she can give you a little guidance around that.

And then I also -- just a reminder for those submitting public comments of which we hope that will be all of you. That due date is November 12th. And there's information around submitting comments also in your folder.

A few other things. I do want to note that Wi-Fi is not available in this room or I think the breakout rooms, but it is available in the hotel lobby. In regard to parking I believe that there is -- perhaps I think there's a discount. You can talk to the people at the front desk about that.

Also for lunch today it's very nice, the hotel's offering a buffet. And I just want to mention that because that's kind of an easy and fast way to get a really great lunch.

And then, of course, you know, standards, restrooms are across the hall. Always be aware of where an exit sign is just as a routine safety matter. And if you can silence your cell phones it always, you know, can be a bit embarrassing if they go off while someone's talking and as -- just as a courtesy.

I think that pretty much wraps up for the housekeeping. If there's something on your mind that I haven't covered and you need some assistance, again, Juanita is available and also you can see anybody at the registration desk.

So with that, now we're going to turn to our folks who are offering opening remarks this morning. It's truly my pleasure to introduce our first two speakers. We have Susan Mayne, who is our Director, FDA Center for Food Safety and Applied Nutrition at CFSAN.

So, Susan?

MS. MAYNE: Good morning. I first want to thank the team that's pulled together all the logistics behind this meeting. There's a lot of work that goes into pulling off a public meeting like this so I just want to acknowledge all the hard work that's gone into putting this together.

And then welcome to everybody here today. Welcome to today's public meeting on Horizontal Approaches to Food Standards of identity Modernization. And also as a Cornell alum I want to also welcome the Cornell students who are participating remotely. Go Big Red!

It's been about a year and a half since FDA launched our multiyear nutrition innovation strategy as an important part of our efforts to reduce preventable death and chronic disease related to poor nutrition. The NIS as we call it, Nutrition Innovation Strategy, continues to be a high priority for Acting Commissioner Ned Sharpless and for me.

One way to reduce preventable death and chronic disease related to nutrition is to empower consumers with

information to make healthy food choices. We have made much progress in many important areas such as putting calories on the menu, implementing the first major update to the nutrition facts label, modernizing claims, and continuing our efforts to reduce sodium in foods. And we are close to proposing a new definition for the "healthy" claim on food labels. And we have been working diligently on the claim "natural."

Another way we are seeking to reduce preventable death and disease related to poor nutrition is by encouraging industry to innovate, to produce healthier foods that consumers want. As part of this effort FDA is exploring ways to modernize our Standards of identity. We know that many standards were established decades ago and have not been recently amended to reflect changes in consumer expectations or opportunities for innovation including the ability to produce healthier foods.

We want to modernize our Standards of identity Program in a manner that will protect consumers against economic adulteration, maintain the basic nature, essential characteristics, and nutritional integrity of food, and promote industry innovation and provide flexibility to encourage manufacturers to produce more healthful foods.

We can do this without input from you. Fortunately we know that many of our stakeholders are interested in this topic. It looks like a pretty full house today and we have hundreds of participants joining us via webcast.

We appreciate the dialog we had at our July 2018 public meeting on the Nutrition Innovation Strategy where we held two sessions on Standards of identity. We look forward to building on those discussions and we expect a vibrant dialog today.

One of the themes that emerged from the 2018 public meeting relates to horizontal standards, our main topic for today. Participants indicated that given our FDA's limited resources and the hundreds of Standards of identity that exist updating every individual standard may not be a feasible modernization strategy.

Horizontal standards which cross categories of

standardized foods would allow FDA to efficiently make broad changes that it could impact many standardized foods. We agree that a horizontal approach is worth pursuing especially when it comes to facilitating industry innovation and encouraging the production of more nutritious foods. That does not mean we won't change individual Standards of identity as appropriate, but horizontal standards make sense given our modernization goals.

Before we move forward with the agenda, I will mention that there were other examples of activities related to Standards of identity underway of CFSAN. For example, FDA is working on a final rule to amend the standard of identity for yogurt to, among other things, better facilitate technological advances in the industry. We are also working to revoke the Standards of identity for French dressing and for frozen cherry pie.

Additionally, we plan to reopen the comment period on the 2005 proposed rule on general principles and food standards modernization. The general principles would establish criteria to use in evaluating whether to establish, revise, or eliminate a food standard. We look forward to engaging with all of you on this important topic in the future.

As a separate matter, CFSAN has issued a request for information entitled Use of the Names of Dairy Foods in the Labeling of Plant-Based Products to help FDA understand how consumers use plant-based products with names that include the names of dairy food such as milk and cheese.

We issued this notice to obtain data and better understand whether consumers are aware of and understand differences in the basic nature, characteristics, ingredients, and nutritional content of plant-based products and their dairy counterparts.

FDA received more than 13,000 comments in response to our request. And we are currently reviewing the comments and information provided to determine our next steps in this area to ensure that consumers are not misled.

We are also working to make sure that our efforts on Standards of identity are aligned with other

related initiatives underway, that I mentioned earlier such as updating the healthy claim and sodium reduction. For example, are there horizontal approaches where industry could substitute certain ingredients in a product, and we could still consider it a standardized food?

For instance, some companies might want to use a salt substitute for part of the sodium chloride in a product to promote sodium reduction. We want to be sure that our recommendations for modernizing Standards of identity align with and build upon other ongoing nutrition innovation strategy work.

In closing, I'd like to take this opportunity to thank Rosalyn Murphy-Jenkins from USDA who's joining us here today. She's director of the labeling and program delivery staff at USDA's Food Safety and Inspection Service.

As you know, USDA has its own program for issuing Standards of identity or composition for meat and poultry products. We look forward to partnering with USDA as we pursue modernizing our Standards of identity.

I'm going to turn the mike over to Rosalyn to present from USDA. Thank you.

MS. MURPHY-JENKINS: Thank you, Dr. Mayne. Good morning. It is a pleasure to be here today to provide opening remarks and to participate in this public meeting on very important subjects. I am here from the USDA's Food Safety and Inspection Service, or FSIS, to show support for the FDA's efforts to explore a horizontal approach to modernizing food standards.

FSIS believes the information gleaned from today's meeting will be helpful to the segment of the industry that falls under our jurisdiction which includes establishments that produce meat, poultry, and egg products and the public that consumes these products.

As this audience likely knows, FSIS and the FDA share responsibility for ensuring that food labels are truthful and not misleading. To that end, food standards have been established to ensure that products sold under particular names have the characteristics expected by consumers.

Food standards are typically established under

the common and usual names of a food and may be defined by certain ingredients both mandatory and optional and sometimes the amount of each ingredient. FSIS has established approximately 80 meat and poultry standards including Standards of identity for hamburger and hotdogs.

As the director of the labeling staff at FSIS, I have observed the many different ways such food labeling standards affect the food products the agency regulates. Industry has and continues to use innovations and technology to develop food products that are not only safe and wholesome, but that are also appealing to the public that consumes them.

As many of you know, meat, poultry, and egg products labels need to be approved prior to their use on products that are introduced into commerce. To accomplish this, FSIS operates a prior label approval system. Under this system certain labels are submitted to FSIS for approval for use while other labels are generically approved.

Generically approved labels are those that bear only mandatory labeling features, they do not contain special statements or claims, and comply with the agency's labeling regulations and/or the Food Standards and Labeling Policy Book.

Generically-approved labels do not need to be submitted to FSIS for prior approval. As you can imagine, this allows for us to see a lot of labels. It also provides us with insight into how the meat and poultry industry is developing products using existing food standards in the regulations and those in our policy book.

As Dr. Mayne mentioned, in 2005 FSIS and FDA jointly proposed a rule entitled Food Standards General Principles and Food Standards Modernization as a first step towards modernizing outdated food standards. FSIS and FDA collectively received 32 comments to that proposal.

Since that time FSIS has received numerous requests from industry to make changes to our food standards regulations and our policy book. As a result, on November 7th, 2013, FSIS announced it would no longer

add new entries to our policy book but would continue to amend and remove items in this book as necessary while conveying new policies through other means such as industry guidelines.

In the recent past FSIS has amended its policy book to include revisions to the standards for chicken cordon bleu and removal of entries for Smithfield Ham and jambalaya.

Most recently, FSIS announced its intention to propose labeling requirements including a standard of identity for cell-cultured meat and poultry products through a public process, likely rulemaking. This process will be informed by the thousands of public comments already submitted to FSIS regarding the labeling of these products.

In conclusion, FSIS intends to continue working with FDA on these issues and we look forward to joining the conversation and learning more about horizontal standards. We are hopeful that the feedback received today will assist our respective agencies with developing strategies to address modernized food standards for the new and innovative products that are and will be coming to market.

Thank you.

MS. BARRETT: I know that the two of you will need to step down, but I really want to share our appreciation of having our leadership here from both FDA and USDA, so thank you. Yeah.

I'm going to call up our next two speakers. These are subject matter experts on Standards of identity. So if y'all can come up and then we'll introduce you. And we're going to jump into some background on the issue, give a little bit of status, and talk about the relationship of SOI to nutrition.

All right. Our next two speakers we're going to start off with Andrea Krause who's a Food Technologist at our Center for Food Safety and Applied Nutrition. She's in our Office of Nutrition and Food Labeling.

And she's going to be followed by Claudine Kavanaugh who is our Senior Advisor for Nutrition Policy in the FDA Office of Food Policy Response. We're going to start with Andrea, again, to give some background and

current status on SOI.

DR. KRAUSE: Thanks, Kari. As Kari mentioned, I'm going to talk a little bit about the history of Standards of identity and the current status of the project. I'm a little bit under the weather so I may pause to get a drink of water. And I'm going to speak quietly so hopefully the microphone can pick it up.

So we're going to take a look back in time today and we're going to go time traveling so hopefully everybody's had a strong cup of coffee and is wearing sensible shoes. I'll have you back in time for the next presentation. We're going to start in the 1900s and work our way back to today. And all of the photos I've taken are from the National Archives.

In 2011 the National Archives had a great exhibit called "What's cooking, Uncle Sam?" Hopefully many of you were able to see that. And if we have some extra time during our time travel maybe we can make a stop.

Before the industrial revolution most foods were produced in the home and many homes were involved in farming. As folks began to work outside the home, food products were increasingly produced on a larger scale which gave rise to food processing and distribution industries.

Consumers did not know how the foods they were buying were produced or what ingredients they contained. A patchwork of state laws were enacted to protect the public and facilitate marketing of mass-produced foods.

At the Bureau of Chemistry which was then part of USDA -- and also a predecessor of FDA, there was concern over harmful chemical additives being used in foods and unethical practices. While over 100 bills were introduced between 1879 and 1906, no legislation was enacted. The Bureau of Chemistry received funding to study the adulteration of foods and produced 200 recipes for common foods.

On June 30, 1906, the Pure Food and Drug Act was passed. On that same day the Meat and Inspection Act of 1906 was also passed. The Pure Food and Drug Act and the Meat Inspection Act divided food regulation into two bureaus; the Bureau of Chemistry headed by Harvey Wiley -

- and that name is probably familiar to many of you -- and the Bureau of Animal Industry.

Three forces seemed to have been at play to push this legislation to fruition where the previous bills had failed. There was a big consumer movement; the publication of *The Jungle* by Upton Sinclair and Harvey Wiley himself was supported of the legislation.

The Pure Food and Drug Act prohibited a food product if it contained any added poisonous or other added deleterious ingredient which may render such article injurious to health. It was intended to prevent adulteration in the form of dilution, substitution of a valuable ingredient, concealment of inferiority, or use of harmful ingredients in foods. It established definitions for adulteration and misbranding and subjected foods to seizure if they were in violation.

The Pure Food and Drug Act prohibited products containing filthy ingredients and regulated misbranded foods against false and misleading information on the label. However, it did not require that foods have an ingredient statement which did not allow consumers to have a means for comparing foods. Additionally, the government did not have the ability to establish mandatory standards; although they did establish advisory definitions. But it was difficult to show a product was in violation.

During this time there was a proliferation of cheap foods which could legally be sold under meaningless distinctive names. The inability to establish mandatory standards limited the government in its attempts to maintain the integrity of the food supply.

In the intervening years the shortcomings of the 1906 Act became apparent and a new statute was needed to ensure the integrity of food by keeping economically adulterated foods off the market. Enter the 1938 Federal Food, Drug, and Cosmetic Act.

Section 401 grants the authority to establish food standards to prevent economic adulteration and ensure that foods meet consumer expectations. Section 401 states: "Whenever in the judgement of the secretary, such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations

fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality and/or reasonable standards of fill of container."

Oops, sorry. I was one behind. I'll just leave this one up for a second. I would also like to highlight several other relevant sections of the Food, Drug, and Cosmetic Act.

The misbranding provision of 403(g) which pertains to food which purports to be or represented as a food which has a standard of identity. A food is considered misbranded unless it conforms to the standard -- the definition in the standard and bears the name of the food specified in the standard and the optional ingredients.

And Section 701 pertains to the administrative procedure required to issue, amend, or repeal food standards.

So what did the FD&C Act mean in practice? Ingredient labeling was required only for optional ingredients. State laws were not preempted so federal standards provided only minimum standards and states could adopt more stringent ones if they wanted.

A product that was purported to be or was represented as a standardized food but did not conform to the definition in standard could not be sold or it had to be labeled as imitation. Consumers could rely on a common name which identified comparable products. As more brands came into distribution this was helpful. Standards created a level playing field for food producers in that a minimum amount of valuable ingredients was required by many of the standards.

As I mentioned previously and as we heard from Rosalyn previously, food regulation was divided into two parts; -- Federal Meat Inspection Act. It still exists this way today.

While I won't be speaking about any of the specifics, I wanted to acknowledge that our colleagues at USDA FSIS have established standards for certain meat and poultry products under 9 CFR.

FDA has adopted 280 Standards of identity in

the years since the passage of the Food, Drug, and Cosmetic Act. Individual standards vary quite widely in their content. The early years of food standards are often referred to as the recipe period due in part to the more simple ingredients used in food processing which was comparable to what was used by home cooks.

Standards establish the name and define the nature of the food in general. Food standards may include mandatory and optional ingredients, minimum levels of valuable constituents and maximum levels of water or filler-type ingredients added nutrients, specific methods of analysis, and they may designate manufacturing processes when that has a bearing on the Standard of Identity of the finished food.

In early 1939 multiple public hearings were announced. Among the earliest products of interest were those shown on the screen. As you can see, many of them are canned and preserved foods that were previously probably made in home kitchens.

The passage of the Food Additives Amendment and Color Additives Amendment instituted premarket approval of food additives and color additives. FDA developed this safe and suitable policy in 21 CFR 130.3(d), which provides that ingredients used in food must be listed food or color additives or generally recognized as safe and used at levels no higher than necessary to accomplish their intended functional affect in food. All safe and suitable ingredients used in the standardized food must be declared on the label.

FDA first applied this policy to the standard for frozen raw breaded shrimp by allowing safe and suitable batter and breading ingredients. 130.3(d) allows manufacturers considerably more flexibility in selection of ingredients.

Since this policy was established, many standards have been revised; however, some have not been updated and they only allow specific ingredients within a category of functional ingredients. For example, they may only allow specific preservatives, acids, or sweeteners.

In 1977, a major recodification of regulations resulted in the Standards of identity being republished

and renumbered. I've included a screenshot of the Federal Register notice with a glimpse at the renumbering that occurred.

I mention this because if you look up a specific standard in the CFR you will see the dates that the standard was modified at the very bottom of the regulation. The oldest date listed for many standards will be this 1977 date; however, most were promulgated before this time.

If you're looking for specific information about a standard and would like to obtain the preamble, you might consider starting with this 1977 preamble to find the original number of your standard and then working backwards from there.

Speaking of the modern standards, up on the screen is half of the 21 CFR citations where the food standards reside. As you can see, the list includes a wide range of foods. Many of these sections contain multiple foods. Milk and cream in Section 131, for example, contains 20 different foods.

This is the other half of the citations. Some of the other sections only contain one standard. So 165, which is beverages, only contains the standard for bottled drinking water.

We've been talking a lot about the food standards in general and I wanted to include this look at the full list for those in attendance who may not be familiar with the types of food that are covered by the standards. Many staple-type foods are covered by the standards including your entire peanut butter and jelly sandwich.

In 1990 the Food, Drug, and Cosmetic Act was amended in several important ways. 403(i) was amended to remove the language that limited full ingredient labeling to non-standardized foods. 403(i) was also amended to require that certified color additives be listed by their common or usual names rather than collectively as colorings.

403(a) was amended such that states may not establish or continue in effect a Standard of Identity for which a food that is the subject of a federal Standard of Identity if the state standard is not

identical to the federal standard. That's a tongue twister.

Changes to 701 removed the formal rulemaking requirements for many foods. And in addition to the aforementioned changes which were specific to standards, the 1990 amendments also established that virtually all foods were required to bear a nutritional label giving the consumer significantly more information about the composition of their foods than they previously had.

In 1993, FDA amended the food standards as necessarily in Sections 131 through 169 to require label declaration of each ingredient used in these foods except for those ingredients that are exempted. Several other labeling changes were made in 1993, some of them relatively specific. And I'm included them on this slide.

FDA also amended certain standards in this 1993 regulation including for dairy products, maple syrup, and canned tuna.

Additionally in 1993, FDA established regulations defining nutrient content claims. Having established uniform definitions for these terms, the agency was able to establish a general definition in 130.10 which permits modification of a standardized food to achieve a nutrition goal and allow the food to be named by the use of a nutrient content claim -- defined by FDA in Part 101.

130.10 allows manufacturers additional flexibility to formulate healthier products without the need to request a temporary marking permit or petition to amend a Standard of Identity.

Several years after NLEA in 1995 and 1996, FDA and USDA FSIS each published an advanced notice of proposed rulemaking in the Federal Register. The agencies were considering how to provide additional flexibility in foods while continuing to promote honesty and fair dealing in the interest of the consumer.

The agencies requested public comment on the utility of food standards naming conventions and they provided alternative approaches which could be considered. At that time the agency presented five options.

The first was to regulate all foods as non-standardized foods; the second to require declaration of the percentage of all major ingredients as an alternative to minimum composition requirements; the third, to require percentage labeling of characterizing ingredients in the food name; and the force -- the fourth, to establish compositional standard for the parent product; and the fifth proposal was the establishment of generic food standards.

The agency received many substantive comments to the ANPRM. Most but not all supported the concept of retaining food standards in some form. The comments underscore the importance of standards to protect and inform consumers, to ensure fairness for food producers, and provide harmonization for interstate and international trade; however, few comments supported the food standards in their current form. Many comments provided feedback on how food standards could be simplified, more flexible, or clarified.

To summarize this long list the commenters proposals included allowing flexibility in ingredients, making changes to specific standards, rescinding or revising them, using advisory committees or other methods to do this, establishing guiding principles for reviewing or revising food standards, and many of the comments requested the FSIS and FDA have a consistent approach to standards.

After the ANPRM, FDA formed a task force and then a joint working group with FSIS. The group determined that the most suitable option at the time was to draft general principles to use when revising, eliminating, or establishing food standards in response to petitions submitted by external parties or on FDA or USDA initiative.

In 2005, the USDA and FDA proposed a joint rule which included 13 general principles to consider when establishing, revising, or eliminating food standards. The general principles have been developed to be consistent between FDA and USDA, but they are not identical. Because FSIS and FDA regulate different products the principles are specific to the particular agency and were developed to reflect the agency's

regulatory needs and perspectives.

These principles could be applied to either Citizens Petitions or agency initiatives. A petition to establish or revise a food standard in Parts 131 to 169 would need to be consistent with all the general principles that apply.

I'm not going to go through the 13 principles specifically, but you can find them fairly easily on the FDA website or using the Federal Register citation. These principles were discussed as part of FDA's July 2018 public meeting.

Again FSIS requested comments both on the general principles and on how best to implement them. On the FDA side of the docket we received many comments. Most generally supported the idea of establishing general principles. Many comments included input on the specific principles. Multiple comments stated that the agency should allow greater flexibility in food standards beyond the principles that were proposed since the principles only applied to Citizens Petitions, process, or agency initiative to modify food standards.

Following the closure of the comment period on the proposed rule and as a follow up to the comments they submitted on the docket, the Grocery Manufacturers Association along with 11 cosigning organizations submitted a petition to FDA and USDA FSIS requesting an approach to modernizing food standards that would allow flexibility across food standards, a horizontal approach which would allow multiple standards to be updated at one time.

The petition proposed six categories of variations that could be permitted to provide flexibility. The proposal touches on the addition of ingredients solely for technical, non-distinctive effects, the use of safe and suitable flavors and flavor enhancers where appropriate, advanced or more efficient technologies to produce ingredients, the use of alternative manufacturing processes, changes to a product's basic physical shape, improvements in nutritional properties that do not rise to the level of a defined nutrient content claim or the use of nutritious ingredients.

The proposal is specific and nuanced and I wanted to touch on each of these six areas, but I would encourage you to read the petition and its appendices for a more complete understanding. It's probably apparent to you based on the name of the public meeting we're at today, but FDA is still considering the horizontal approach proposed in this petition as well as other approaches for modernizing food standards.

I'm going to speed forward in time to 2018 and while modernization of food standards was, of course, on our minds during the gap, it was also stacked high in our offices and filing boxes. FDA was working on many other labeling and nutrition-related initiatives during this time.

Our work on standards publicly reemerged in 2018 with the announcement of the Nutrition Innovation Strategy. The next presentation will cover the Nutrition Innovation Strategy in more detail; however, I wanted to highlight on our timeline the advent of the Nutrition Innovation Strategy.

FDA has committed to finding new ways to reduce the burden of chronic disease through improved nutrition. Last summer FDA held a public meeting about several facets of NIS including breakout sessions about Standards of identity with discussions of the 2005 proposed rule. Many of you participated in that meeting and provide substantive information and written comments on the docket. FDA has reviewed these comments and is using them as we work to proceed on Standards of identity Modernization and other nutrition priorities.

This brings us back to 2019. See, I told you I was going to bring you back. If you're familiar with the unified agenda, you may have noted several food standard related activities listed here. These are still in process as Dr. Mayne discussed earlier.

FDA staff have also been engaging with stakeholders who have reached out to us with interest about specific standards by holding listening sessions. And, of course, our reason for gathering today for an engaging discussion of food technology, nutrition, and consumer expectations related to food standards. So hopefully you've had a vitamin donut and you're full of

pep and vigor and ready to discuss.

I would be remiss if I didn't remind you about your homework is to make comments to the docket following this meeting. And with that, I will close. Thank you.

DR. KAVANAUGH: Hello. Glad to be here today. I'm going to talk mostly about Standards of identity and Nutrition, but I did want to kind of bring you back a little bit to the Nutrition Innovation Strategy. And I know our last couple speakers have talked about that, but I did want to give a little bit more information.

So in March of 2018, FDA announced the Nutrition Innovation Strategy to reduce preventable death and disease related to poor nutrition. So the key goals of the NIS were to empower consumers with information and also facilitate industry innovation towards healthier foods that consumers want.

And the agency is really committed to engaging stakeholders to explore how we can best promote public health through this process such as today's meeting and in the evolving food and beverage marketplace.

Just to give you a little bit of an idea of how we kind of look at nutrition at FDA, kind of our conceptual framework, I wanted to show this little schematic. The agency always starts with robust science. We look and see what tools do we have, in -- like, our toolbox that we can use.

One thing that we have a lot of is being able to control nutrition labeling. We use that. The labeling can increase the consumer understanding. An example would be like the nutrition facts label, the updated nutrition facts label. We hope that increase in understanding will lead to behavior change and then our ultimate goal of having a public health outcome. And in this case reducing the risk of disease and death related to poor nutrition.

Another way that we could use things in our toolkit are things with reducing sodium or we banned partially hydrogenated oils. Those both can make a more nutritious food supply which then can have the impact with public health. And then you kind of have a feedback loop because you have the changes in public health and how our policies affected that and that contributes to

the robust science.

I know Dr. Mayne already talked a lot about our nutrition, the elements -- the key elements, so I'm just going to go through these quickly. But modernizing claims and ingredient labels, implementing the nutrition facts labels and menu labeling, reducing sodium, and of course modernizing Standards of identity, why we're here today, were the major reason -- are the major elements of the Nutrition Innovation Strategy.

And since we had our public meeting last year, we've actually gotten a lot done so I wanted to take just a couple minutes today to kind of highlight some of the accomplishments that we've had already in just the 18 months that we've had the initiative.

We had a public meeting last July in 2018 where we talked about all the different topics and were able to get feedback through the docket, as well as the different sessions we had public comment, we had breakout sessions like we're having today. So we are utilizing all the information we've gotten.

We've published numerous final guidance documents for updating the nutrition facts label and we also published final guidance for menu labeling. We have started consumer education for menu labeling and that's on our website. So I would definitely recommend that you guys go to that.

We're in the process of updating our educational materials for the nutrition facts label and are working on an education campaign for that as well. We have to wait -- the compliance dates for the nutrition facts label are still coming so we're waiting till those happen to start the education.

We also published a guidance on the naming of potassium chloride salt. We're continuing our work on sodium reduction targets. And as Dr. Mayne said, we're close to having a proposed rule on the claim "healthy."

So now, kind of transitioning a little bit into how does the nutrition innovation strategy go with the Standards of identity. So Standards of identity Modernization is just a critical component of NIS. There are over 280 Standards of identity. And I know Andrea showed you the huge list and everything that has to be in

a peanut butter and jelly sandwich has a Standard of Identity. So a lot of products have that.

And outdated Standards of identity I think we could definitely see from Andrea's walk through history some of these were done such long ago some of that -- those outdated standards can really stifle innovation and prevent manufacturers from producing healthier versions of standardized foods.

So we used the public meeting last year to discuss the Nutrition Innovation Strategy and had two breakout sessions specifically on the Standards of identity Modernization. And just some general feedback that we got from that meeting was a lot of support for this horizontal modernization.

The feedback that we got said that it would allow FDA to make changes efficiently across categories of standardized foods to advance our nutrition goals. If you made changes individually you would have to do rulemaking for each of the 280 standards. So as I'm sure most people in the room know and on the webcast, rulemaking takes a long time.

So we also got a lot of comments to the docket as well. We had over 3,700 comments. And we used the information from those comments to inform our public meeting today. So you'll see we're able to really build on the feedback that we had last year in planning this meeting.

Now I'm just going to talk a little bit about the horizontal approaches. So when we say a horizontal approach what do we really mean? The horizontal approach really identifies changes that would permit flexibility across all or broad categories of the standardized foods.

So an example kind of would be we could -- and this example actually came from the comments that we got to the docket. That we could permit salt substitutes in cheeses. So the products that would be impacted would be all the standardized cheeses that have a mandatory salt requirement. And then if we changed it and allowed them to use a salt substitute they could make modest reductions in sodium across a broad category of cheeses and this would lead to the ultimate goal in the Nutrition Innovation Strategy to reduce your sodium.

The next one is how Standards of identity and nutrition kind of cross is standards can be used to ensure that a food meets nutritional expectations. So we have a requirement for mandatory Vitamin D fortification in evaporated milk. And this is kind of an old rule, but it requires -- FDA requires the fortification of Vitamin D in evaporated milk because it's used in infant feeding programs and because the practice of fortifying evaporated milk products with Vitamin D was accepted by nutritionists. So as I said, this is an old example, but it really illustrates how our standards can help ensure foods provide the nutritional components that consumers expect.

The functions of Standards of identity are to really protect against adulteration and maintain the integrity of food, but it also reflects the consumers' expectations about the food that they have. And that includes nutrition.

Another area that Andrea already hit upon this is nutrition and Standards of identity can be used to support healthy diets. So as Andrea already illustrated, the nutrient content claim regulations permit the modification of standardized foods to achieve a nutrition goal.

So just an example of this would be you could reduce the fat or calorie content of food and call it fat free or low calorie to meet a nutrient content claim. And this is actually an example of how FDA considers a horizontal approach to work to modernization as this type -- this regulation covers changes that could be made broadly across different standardized foods. And we actually explained in the rule that we took this action to provide consumers with greater varieties of modified foods in order to help consumers maintain healthy dietary practices.

Another way that standards and nutrition can kind of intersect is addressing a documented public health need. So as in 1992 the Public Health Service recommended that all women of childbearing age consume 400 micrograms of folic acid a day to reduce the risk of pregnancies affected by spina bifida and neural tube defect.

Following the recommendation FDA formed a subcommittee on folic acid and also an advisory committee to look how we can help assist women to get more folic acid. So after really reviewing all of the recommendations FDA determined that developing and implementing a fortification program to add folic acid to the food supply would be effective way to overall increase the folic acid consumption of women of childbearing age.

And we also found that through the fortification of grains and related products that would help the goal, but also it would keep the daily intakes for non-target populations below -- within recommended safe limits.

So FDA has -- continues to monitor the health effects of folic acid fortification. And more recently we've allowed the fortification of corn masa flour. But the addition of folic acid to standardized and enriched grains has led to an improved folic acid intake, improved serum levels, and a decrease prevalence of neural tube defects in the United States. This is probably one of FDA's real true success stories and it intersects with Standards of identity.

Standards of identity also we recognize that our standards have impacts on other feeding and nutrition programs in the government. The USDA Agriculture Marketing Service purchases a variety of food products called USDA Foods and they develop technical requirements for these foods and many reference our FDA Standards of identity.

So for the Food and Nutrition Service that manages nutrition assistance programs as well as the school lunch programs they reference our Standards of identity for when they're purchasing different products.

Similarly, the Department of Defense also references our Standards of identity when they're purchasing and doing procurement of food for military bases and ships and other military facilities. So they have specific specifications of what these foods have to have and these come back to our Standards of identity.

So we -- this is something we definitely have to keep in mind because changing the Standards of

identity will impact the USDA's standards as well as the military standards that they have on the quality and nutrition of foods in the federal program. So changing the Standards of identity can really have I guess a cascading affect and that's something we want to keep in mind.

And I would kind of highlight in our breakout sessions that we have later today that when we talk about specific changes to horizontal changes or specific changes to specific products to kind of keep this in mind how the changes of Standards of identity could have impacts more broadly.

So just to kind of sum up the Standards of identity Modernization goals, we still want to always protect consumers against economic adulteration and maintain the basic nature and essential characteristics and nutritional integrity of the food, but through modernizing them we want to have -- allow the industry to have more innovation and provide more flexibility to encourage manufacturers to be able to produce more healthful foods.

So that's our ultimate goal today and we're hoping throughout our breakout sessions and our discussions and public comment we'll be able to get some more insight from our stakeholders to help inform our future actions.

So I'm going to hand it back to Kari.

MS. BARRETT: Okay. Thank you, Claudine. That was really great. That was I think super helpful to go through that key foundational information. I really love the photos, Andrea, that you found. And probably all of you are wondering how do I have access to these great PowerPoints?

They will be posted on our website. It does take often a few days or more. So do visit our meeting webpage for those, but it may be towards the end of next week if not sooner. But give us a couple of days to get those up there. But, again, appreciate that.

We're now going to move into a Q and A session, kind of wake everybody up. Give you an opportunity to ask a few questions before we go into breakout sessions. I'm going to ask our other panelists for the Q and A if

they'll come up and we'll go ahead and introduce you.

Okay. And now Juanita's putting up some tent cards here. And we've retained Claudine and Andrea and Rosalyn is going to come back to join us for this panel. We also have Doug Balentine. He's our Director of our Office of Nutrition and Food Labeling at CFSAN, Daniel Reese who's a Team Leader of our Product Evaluation Labeling Team also in the ONFL office, and then Megan Velez who's our Acting Director of our Office of Regulations and Policy at CFSAN.

So I want to welcome the FDA and USDA group that's here to answer your questions. I'm going to kick us off. I have one question that I'm going to ask just to kind of warm the session up. But you can see there's a couple of microphones in the room so, again, you can feel free once I've asked a question to come up to the microphone. It's just a chance to if there's something on your mind you think would be helpful as we then go into the breakout sessions, we really welcome that and, again, welcome your participation throughout the day.

It's always fun to be in the position of asking the questions. So I want to start out because we have covered a lot of sort of historical ground. And, Doug, this question’s going to be for you.

As noted in 2005, FDA and USDA jointly issued a proposed rule entitled Food Standards General Principles and Food Standards Modernization. And this rule was proposed to set out some general principles that if finalized both agencies would consider when determining whether to establish, revise, or eliminate a food standard of identity.

What exactly is the status of this proposed rule that we've talked about?

DR. BALENTINE: Yeah. Thank you, Kari. I think you've already heard about this rule twice this morning. Rosalyn mentioned it in her introduction and Andrea also included it as part of the long history we've had in standards.

No. We view this rulemaking as an important step that can be used to support modernization of standards in general. And we did include some information around our intentions around this standard in

the spring 2019 unified agenda.

And given the time that's elapsed since the proposed rule had been put out, that was in 2005 and as you heard there weren't all that many comments at that point in time, we thought that before we took a decision to finalize or move along or how to best move forward with that rule it would be a good opportunity now to reopen that rule to get additional comment in light of the long period of time.

So there's intention to work towards doing that and we will work together with USDA to continue to progress this rule forward. So thank you.

MS. BARRETT: Great. Thank you, Doug. All right. Do we have a question from the audience? If you want to come up to the microphone? Great. And if you'll state your name and affiliation when you ask the question.

MS. SIMON: I'll be brave and go first.

MS. BARRETT: Thank you.

MS. SIMON: Michelle Simon. I'm with the Plant-Based Foods Association. I just have a clarifying question about what you mean by horizontal approaches because I was thinking more -- well, I'm wondering if you met more across the whole all food categories because what you showed in that slide was about one category.

So I'm just curious when you say "horizontal," do you mean within one category or across different food categories?

MS. BARRETT: Great. Thank you for asking that. Dan, is that one that you can take?

MR. REESE: Thank you for the question. Yes. So revising individual standards some stakeholders have referred to this as a vertical approach to updating can be resource intensive for FDA and stakeholders.

So in comparison horizontal changes that would permit additional flexibility across all or broad categories of standardized foods such as horizontal approach would require less time. A horizontal approach would help FDA efficiently make comprehensive changes that could impact many standardized foods.

As an example of the horizontal change that stakeholders have proposed is allowing salt substitutes

as we have mentioned earlier in a couple of the presentations.

I do note that while FDA is particularly interested in discussing horizontal changes to Standards of identity today, we do recognize that changes to individual standards may be needed. FDA will continue to update individual standards as resources permit and as agency priorities dictate. Thank you.

MS. BARRETT: Thank you, Dan. I don't know. Does anyone else on the panel have anything to add to that? Good? Okay. We're going to go to our next question.

MS. FRYE: Yes. Cary Frye, International Dairy Foods Association. I have a more general question. As we know today food is traded around the world. And the U.S. has been engaged with the Codex Committee on Food Labeling over many, many years.

And I just wondered if you had any comments related to Codex standards and how they impact U.S. as far as when you're looking at modernizing standards. I know there are provisions to review Codex standards, but some of the Codex standards are very developed and do have some principles for flexibility.

And I just wonder how Codex standards might impact your work in modernizing U.S. standards. Thank you.

MS. BARRETT: Great. Cary, thank you. Doug, did you want to speak to that?

DR. BALENTINE: Sure. I think since I'm the U.S. delegate to both the Codex Nutrition Committee and the Codex Food Labeling Committee, you know, I try to keep involved with the Codex work. And I think what we try to do is we bring our thinking to the discussions in Codex. And as we look at what we might do we also often times take what thinking and discussions have gone with Codex into account as well.

So where we can make use of thinking in Codex we oftentimes do, but it's in some cases we need to take action that would be slightly different from Codex because of the needs of the U.S. marketplace and the U.S. industry. So I think it's a flexible approach, but we do take them into account.

MS. BARRETT: Great. Thank you. Some more questions.

MR. MARRIOTT: Good morning. Robert Marriott. I'm starting with the IRS in three days, but I'm here as a private citizen. I have a question about a phrase that I've seen occur periodically in the conversation over this including in some of the wonderful presentations we've had this morning which is "consumer demand."

And I'm curious about the role of consumer demand as a rationale or justification for specific aspects of policy changes regarding Standards of identity. What role does consumer demand play in Standard of Identity development?

It didn't appear in the formal framework to identify it and we do know that consumers, despite the best efforts of the community, continue to struggle with comprehension of nutrition. So how does that influence the way that consumer demand or perception or what influences the pursuit of different Standards of identity? Thank you.

MS. BARRETT: Yes. Thank you for your question. Claudine, is that one you can --

DR. KAVANAUGH: I'll take that one. So I know when at least I was talking about consumer demand we're really looking at consumers demanding healthier products. And some of the getting the healthier products, the Standards of identity sometimes are preventing the industry from being innovative and making healthier standardized foods. So that's one thing.

Also with Standards of identity part of it is consumer expectation. So if they have a bread they have certain expectations when they have that bread and that's because of the Standards of identity. So I think it kind of -- the Standards of identity have consumer expectations as well. And some of that in the example I used for the fortified evaporated milk there was an expectation since it used in feeding programs that that needed to be there.

So I think it depends on the standards that we're looking at what the consumer expectations are and kind of consumer demands. But I think a lot of it is they want healthier products and sometimes the standards

can really stifle some of the industry innovation to make those products.

MS. BARRETT: Thank you. Another question? And, again, if you'll state your name and affiliation.

MS. CAMPAGNA: Sure. Good morning. I'm Shannon Campagna. I'm with Van Scoyoc Associates. And my question is about the RFI on use of plant-based -- dairy term for plant-based. Where does that fit in the Nutrition Innovation Strategy? Is it -- do you think of it as a separate effort? Is it part of this effort? Kind of where do those two projects kind of intersect?

MS. BARRETT: Great question. Doug?

DR. BALENTINE: Sure. Thanks for asking that. I think, you know, the intersection is that, you know, there are standardized foods such as dairy foods and cheeses that are there and then we're seeing a lot of movement in the marketplace to innovate. And that's a little bit what standardized -- standardized products are about.

But there's a need to innovation that is also part of consumer demand. And so, you know, we're looking that in the standard space, but we're also looking that as part of the general food labeling work that we do.

And so where we are now is we got a large number of comments to that RFI. We've been reviewing those comments and there was a number of consumer studies that went into those comments that we're evaluating as well. And as we look at that we're going to then take all that collective input and take a decision on how we might move forward either in a space that might lead to something around standards or in the food labeling arena. And we're looking at how to best make sure that consumers get clear labeling in this particular space so that they understand the products that they're buying. Thank you.

MS. BARRETT: Thank you. We have more time. Some more questions? Great. Thank you. Take your time.

MS. MCENROE: Sorry. Diane McEnroe, Sidley Austin. I just wanted to know if you could discuss a little bit about how the TMP process will play into this during this window. Is it still the process you'd like people to be pursuing?

MS. BARRETT: Dan?

MR. REESE: Thank you for the question. Yeah. I believe for the time being we're going to still continue to use the TMP process as it is outlined in the CFR. So thank you.

MS. BARRETT: Thank you for your question. A couple more questions? Turn to the panel. Panel, was there something that you thought you were going to be asked that you weren't asked that you'd like to touch on?

I know that we've talked about whatever steps are taken that there will be plenty of opportunity throughout the process to have public comment and engagement on those steps. There has been a lot of engagement to date and we really appreciated the conversations that we've had with individuals and with groups on this topic as we look to for forward. So just wanted to note that we'll continue in that vein. Lisa, if you'll introduce yourself and your affiliation?

MS. WEDDIG: Thank you. I'm Lisa Weddig with the National Fisheries Institute. And I'm just curious through this process for modernizing standards with the horizontal concept what is the status of existing Citizens Petitions for changes to existing standards?

MS. BARRETT: Okay. Doug?

DR. BALENTINE: Sure. I think Claudine already mentioned it a bit is, you know, we have a number of existing Citizens Petitions that we're working on as a result of -- that relate to standards. So we have the yogurt Citizens Petition that we're actively looking at trying to wrap up finalizing that piece of work which the dairy industry is quite anxious for us to complete.

We have some work that we're doing around the tuna standard for example so that's something that the fisheries group has come in and talked to us about and it's on our radar as something that we need to move ahead.

So we aren't going to stop working on other standards work while we do the Standards of identity work, and we're progressing that sort of work forward in line with our regulatory reform effort, and in terms of priorities on where we think that we can get that work done in a timely manner, and the ones that we think are the most needed to be addressed now versus ones that

might be addressed at a later time.

MS. BARRETT: Great. Thank you, Doug. Yes. We have another question?

MR. GENDEL: I'm Steve Gendel with the Food Chemicals Codex. And I'm curious if you could outline what you're doing to enforce the current standards as they exist.

MS. BARRETT: Thank you, Doug.

DR. BALENTINE: Sure. I think we are, again, along with the resources we have we look at current standards and where we need to enforce them. And particularly enforcing them when we believe there is a public health food safety issue at hand because that would be the biggest priority we would have in terms of taking action where there really is a need.

As you -- as we said earlier, the labeling industry and labeling of products has been changing rapidly particularly with the innovation of new products in the marketplace. And we're actively looking at -- at how labeling can be used to assure that consumers understand that products they're buying and how that overlaps with standards.

And so we're -- that's the balancing act we having in terms of setting priorities and whether we would take action to enforce existing standards versus working to just assure that consumers have the appropriate information they need.

MS. BARRETT: Thank you. Another question? Yeah.

MS. FRYE: Cary Frye, International Dairy Foods Association. During Andrea Krause's presentation she showed a wonderful timeline of a number of different achievements in food standards and labeling. And one of them had to do with looking at the general principles for modernizing standards back in 1997 and then that led to the 2005 ANPR. So that was an eight-year time frame that the FSIS and FDA worked together.

And so my question is more about timing of standards modernization and what the agency thinks how long. I know it is a huge undertaking, but what time frame are you thinking going forward? Is it a year or three years or eight years? Any estimates that you can

provide to us for this effort?

MS. BARRETT: Thank you. Megan?

MS. VELEZ: So I don't think we have an estimate to share today. What we are hoping today is that we get a lot of great information both at the meeting and in the docket to inform our next steps regarding Standards of identity Modernization, in particular with respect to the horizontal approach that we're actively exploring right now.

We did previously talk about the 2005 rule and FDA's intent to reopen the comment period of that rule. Just given the length of time, again, as Doug had stated, since that NPRM published we recognized a lot has changed in the industry and so are interested in hearing from all stakeholders and receiving additional comments on that proposed rule to inform next steps for that rulemaking.

DR. KAVANAUGH: And I will say with the Nutrition Innovation Strategy last year we had the public meeting just on all the topics and a year later we have moved to having a -- just a meeting on this. So you can definitely see it's a priority for the agency.

So, again, we're not going to make specific time things, but I think at least our recent actions show that this is an area that we're making a high priority.

MS. BARRETT: Thank you. I think we have time for one or two more questions. Yes, thank you. Again, if you'll say your name and affiliation?

MR. GLEDHILL: Good morning, Jonathan Gledhill, Policy Navigation Group, but really more asking as a private citizen. I noticed the 2005 proposed rule was listed as a significant -- not all significant under Executive Order 12866, but not an economically significant document.

As part of your update given the public health goals here and the significant impact, do you plan to update that classification to make it an economically significant document as well as comply with the other OMB requirements on executive order and statutory things on executive -- on regulatory review since 2005?

MS. VELEZ: So I think with respect to the 2005 rule, the next step for us at least as we've stated is to reopen the comment period. So as part of, you know, we

will take the information that we use -- receive as part of that to inform, again, our next steps whether that be a reproposal or moving to a final rule.

In either of those cases there is we would follow all the applicable requirements of the executive orders in terms of economic analysis and other regulatory reform mandates.

MR. GLEDHILL: Thank you.

MS. BARRETT: Thanks. Another question?

MS. BOOREN: Good morning. Betsy Booren, GMA. I'd be curious how -- we see a lot of activity currently going on in the states as they are defining products, setting Standards of identity. Any insights on how you have interacted with the states, the Departments of Health or where they fall and they're setting some of these standards or how you might be doing that in the future?

We think it's appropriate for the federal agencies to be doing that and would get a better understanding how you're working with some of the states as these issues as related of Identity are arising.

MS. BARRETT: All right. Thank you. Doug, thank you.

DR. BALENTINE: Sure. I think, you know, often times, you know, the states can begin moving faster than we move at the federal level and they start the ball rolling and then that becomes the basis for us to continue with work.

But we do, through our state outreach, often times consult and work with the states. And we try to make sure that as much as possible the states work is -- can be informed and aligned by our regulations and rules. And so we will continue to do that and cooperate with the states as much as possible while we do our own work to move forward into modernizing standards.

MS. BARRETT: Great. Thank you. I think we have time for one more question. Do we have one more? Great.

MR. TANNER: Yeah. Good morning. I'm Ron Tanner from the Specialty Food Association. I know that you have eliminated frozen cherry pie and French dressing, but my question is does modernizing food

standards mean eliminating some of the food standards?

MS. BARRETT: Thank you, Ron. Dan -- or Doug?

DR. BALENTINE: So we actually haven't eliminated those two standards yet, but it is on our agenda to make them go away as part of our regulatory reform work and responding to petitions. I think, you know, this particular horizontal standard work isn't really about eliminating standards, but through our other standards work when we believe that standards are unnecessary or overly burdensome we would look at eliminating the standards that are unnecessary just as part of regulatory reform.

But the overall objective isn't to necessarily go through and eliminate standards just to eliminate them, but as they fit the overall agenda we would consider eliminating standards when that seems to be appropriate.

MS. BARRETT: Great. Thank you. So thank you very much to everyone who has asked a question. And I hope again that that gives you some information as we go into our breakout sessions later this morning and this afternoon.

I do want to take a little time now -- and actually, panelists, if you'll just stay where you're seated and I'll run through a little bit of information about the breakout sessions. And then we'll actually adjourn for our break a little bit early.

But, again, wanted to note that we do have the breakout sessions. They will begin this morning at 10:30. We're going to be running three breakouts at the same time. They are listed in your agenda with the various meeting rooms. They will then be repeated this afternoon starting at one o'clock.

And I just want to go over again really what the purpose is. I think all of you are prepared for the conversation, but it really is to solicit your input and ideas on the three topics that we've noted today related to the Standards of identity Modernization which are innovation, nutrition, and consumer expectations.

And in the sessions we really want you to focus on this idea of horizontal changes or changes that can be made across categories of standardized foods. And that

will help us achieve the innovation and nutrition goals that we're setting out to work on.

We have heard from several stakeholders regarding specific changes that they're interested in in individual standards. In these breakout sections we want to hear if and how these specific proposals could apply across a category or categories of standardized foods.

Our goal in the breakout sessions is to discuss efficient modernization approaches that will have the greatest potential impact for a wide variety of stakeholders. So, again, we really are looking to solve a problem. There is a problem. The status quo isn't going to work going forward.

And whether it's the horizontal changes or other ideas that people have to modernize these standards we need to hear from you. You've seen the rulemaking process, you've seen the history. It's over 100 years of history on this and we need to move it forward. So how are we going to do that?

And that's what we're looking for you to discuss with us today and to take that bigger perspective. How can we make the greatest change and still keep the protections that we need to have?

So we're really asking when you show up for the breakout sessions to come with an open mind, to be constructive, to be respectful of others. We know everyone's going to have a diversity of opinions and we really welcome that. That's part of the messy process of public policy decision making so that's great.

But we do want to hear from you so do speak up today. I just really want to encourage that. Some of the -- just the specifics of the logistics to keep in mind, again, in your agenda you see it laid out what the topics are. You can choose where you want to go. We are going to start promptly at 10:30.

If you do get to a meeting room and it's already starting to get fairly full and there's an FDA staff person at the door noting that, then if you could perhaps consider attending a different session and then going to the session you originally wanted to go to in the afternoon. We just appreciate that.

We want to keep the numbers in the rooms, you

know, as equally distributed as we can given the large size of this group and the desire to have some conversation.

The only other thing that I would note since you are going to have a bit of a longer break, again, if you'll look at the background materials that were provided to you in the packet. We're giving you a lot of information. We've shared with you some of the ideas that we've already heard.

Are those good ideas? Are they worth talking about? Are they not good ideas? Why? So that will help. We have the specific questions that we're going to walk through so you know what's coming. And, again, we just really are happy that you're here and that you're willing to participate with us.

So with that, I also want to acknowledge the webcast audience. You will have the opportunity this morning to see the conversation on innovation and this afternoon we'll be discussing nutrition in this room. So with that, I just want to thank all of you in advance for your participation.

We are going to take the break now. You will have until 10:30 and then we'll begin promptly with the first set of breakout sessions at that time. So thank you.

(Off the record.)

MS. BARRETT: All right. Thanks, everyone, for your patience. We have a couple of changes in our list of commenters. So for those folks who have that in your package just know it's changed a little bit. We also have a change on our panel.

So we will go ahead and get started. Again, I'm Kari Barrett. I'm with FDA. I am our Team Lead for Public Engagement in our Center for Food Safety and Applied Nutrition. And we do have an FDA panel here today who will listen to the public comment that will be offered.

Folks offering public comment have registered in advance to make a statement and we'll talk about that process in just a moment. But I do want to note who we have here from FDA.

So we have Beth Briczinski who's our Senior Science Advisor for Milk Safety in our Office of Food Safety at CFSAN; Claudine Kavanaugh who you met this morning, a Senior Advisor for Nutrition Policy at FDA. Instead of Andrea Krause who, as you know, did a great job getting through her presentation but she was losing her voice. So I just want to thank Pat Hanson who's here today, our Deputy Director for the Office of Nutrition and Food Labeling at CFSAN has graciously agreed to step in. So thank you, Pat. We also have Daniel Reese again. You've met him this morning, our Team Lead for Product Evaluation and Labeling Team in the Office of Nutrition, Food and Labeling at CFSAN; and Steve Bradbard who if you were fortunate to attend the consumer session you might have met Steve in one of those sessions and we welcome him. He is our Director, Consumer Studies Branch in our Office of Analytics and Outreach at CFSAN. So I want to thank our FDA staff for being here to listen to this comment that will be offered.

And I think some of you are familiar with our process, but what we'll do is we will generally work in the order that is listed on your sheet. But, again, there have been a few minor changes and I'll mention them as we get to it.

What I will do is we used to have people, like, do a big, long line and come up and we thought that's really not very kind or comfortable. So we're just going to call up people one by one. But if you know you're sort of close to being called just, you know, if you can make sure you're in this general area so you can come up to the microphone quickly. That's appreciated.

We do have about 30 people offering public comment today and they have my understanding is four minutes. As you can tell by the numbers of people that that four-minute timeline is important and we ask that you respect that.

If you go beyond four minutes I will note that and I will ask you to wrap up and to just be sure that you have your full comments submitted to the docket. And so I just ask that we work together and people are mindful of the time.

And I think with that we can go ahead and get

started. And we'll begin with our first person offering public comment which is Sarah Sorscher from Center for Science and the Public Interest.

And as you do come up there is a podium here. If, again, you will just say your name fully and your affiliation for the transcript to be sure we have it right.

Sarah?

MS. SORSCHER: So my name is Sarah Sorscher and I represent Center for Science and the Public Interest. CSPI is America's food watchdog and I have no conflicts of interest to declare.

We really welcome this opportunity to engage with FDA on this important topic. Standards of identity have long served as one of the earliest fundamental consumer protections for food developed in an area, of course, when there was rampant food fraud, when consumers had very few such safeguards.

In Poison Squad Deborah Blum recounts how tea could include four sweepings, coffee was comprised of ashes, and milk could include formaldehyde. And some places of the world, of course, still grapple with adulteration that poses serious safety risks.

Since 1938 FDA has developed additional tools to address many of these problems, but such tools are not fully protective. Nutrition and ingredients requirements provide key information, but fall short, for example, in declaring the percentage of high-value ingredients.

This means consumers can't look at a label and identify the percent of a product that's whole grain versus refined grain unless the manufacturer chooses to declare it voluntarily.

Likewise, we have a process in place for FDA to review new food additives, but that process has increasingly been abandoned by companies in favor of the grass loophole which allows for companies to self-certify the safety of their own additives in secret.

In this context, food standards remain supportive of public health. And one recent example of this is the standard for enriched flour which was cited at the beginning of the day. Amendments in the late 1990s allowed the addition of folic acid and various

studies have shown a remarkable population level decrease in the incidents of neural tube defects of 19 to 32 percent depending on the study since the change took place.

It's also important to keep in mind that a market-based voluntary approach may not have the same impact as mandatory standards. In 2016, FDA permitted folic acid supplementation in corn masa flour, but to date no manufacturer has actually begun supplementing. And this is a real public health concern because Latinos who often consume corn masa rather than enriched wheat flour continue to have a higher risk of giving birth to babies with neural tube defects. So we've urged FDA to develop an enriched standard for corn masa to address this disparity.

We've also seen a gradual walking back in FDA's enforcement of food standards over the century and companies are now permitted to develop their own non-standardized foods and set them apart using a common or usual name.

The agency's existing regulatory tools have not always been adequate to protect consumers from being misled by some of these changes. For example, in the bread aisle, products with minimal amounts of whole grain are able to essentially now mimic whole wheat bread which has a Standard of Identity of 100 percent whole grain using names like wheat bread or bread made with whole grains with whole grains in tiny font.

And these names are misleading to consumers potentially who believe these products are whole grain bread and yet they do not meet the Standard of Identity.

We've also seen a proliferation of plant-based products marketed as substitutes for milk. And while we don't think consumers are necessarily misled into believing that these products are dairy products, we've asked FDA to require labeling of plant-based products so consumers can see where they may fall short of the referenced dairy product and key nutrients of public health concern.

And there's certainly room for further improvement for some standards, particularly ones that effectively place minimums on unhealthy but historically

high-value ingredients. This includes milkfat minimums for cheese and dairy products and the soluble solids level minimum for juice, the Brix level, as well as limitations on the use of sodium substitutes.

However, some of these concerns can and should be addressed -- or many of these concerns can and should be addressed on a case-by-case basis that prioritizes changes that will benefit public health rather than through a more crosscutting deregulatory approach.

It's important to ensure agency review particularly for changes targeting nutritional improvements. Currently such changes must be pegged to approve nutrient content claims. And CSPI would oppose, for example, a process that delegates the companies the job of determining when a change provides a nutritional benefit as these views might not be pegged to strong public health evidence. Companies also should not be permitted to make substitutions that they find convenient or profitable without public consideration of the tradeoffs for consumers.

Amending the standards also opens the door for claims that would make it harder for consumers to distinguish between products of high nutritional value and those of lower value. We wonder, for example, how consumers would distinguish between, like, a whole grain macaroni product that was 25 percent whole grain versus one that was 100 percent or tell the difference between flour with Vitamin D and enriched flour.

Changes intended to benefit nutrition can also have unintended consequences. We've been supportive of efforts to substitute potassium chloride for sodium chloride to achieve sodium reductions, but we're also cognizant of the fact that substitution poses a risk to adults with chronic kidney disease.

And in this case, there's actually populate-based models showing that the substitution will be beneficial, but the same considerations might not be true for every ingredient, so a case-by-case assessment is needed.

Finally, we have concerns about the use of safe and suitable ingredients as the standard for new additives. When FDA drafted nutrient content regulations

in the early 1990s there was a presumption -- and in the late 70s, there was a presumption that new additives would be reviewed for safety, but today companies are increasingly using the grass process to self-certify.

And we have been pleased this loophole is currently being legally challenged in court. We're not happy to see these ingredients being added without premarket review to non-standardized foods and certainly would not like to see the door open to including standardized products as well. Thank you.

MS. BARRETT: Thank you. We'll have our next speaker, Betsy Booren.

MS. BOOREN: Good afternoon. I'm Betsy Booren, Vice President for Regulatory and Technical Affairs for the Grocery Manufacturer's Association. GMA represents the world's leading consumer package good companies. The CPG industry plays a unique role as the single largest U.S. manufacturer employment sector delivering products vital to the well-being of consumers every day.

We advocate for rational, informed, uniform regulatory frameworks that are based on risk-based science, promote choice, build consumer trust across the sectors we represent from household products to food and beverage.

A well-designed general horizontal regulation for food Standards of identity by which all standards could be updated instead of a standard-by-standard approach is needed. This type of flexible regulation would allow for broad standards reform, advance new uses of technologies, and provide consistent and clear information to consumers.

We support an approach for modernizing food standards that operates in tandem with current standards, but allows for flexibility with an agreed-upon parameter such as non-characterizing ingredients.

Critical to this approach is setting these general principles. We were going to recommend that you revisit that and would like to thank you for reopening the proposed rule for comments in 2005 and hope that is with FSIS as well.

We believe that having agencies clearly articulate how a new standard will be determined and then

provide flexibility for innovations within any new standard is needed.

This type of approach will promote the efficient use of agency resources, remove barriers to innovation that currently constrain industry right now. Of key importance, it will enable manufacturers to bring consumers a wider selection of traditional foods with innovative nutritional profiles which can help assist them in making choices for their healthy lifestyle.

GMA has provided additional information in our October 2018 comments. The lack of clarity on this issue by FDA has led to an increase of states defining products. This patchwork standard of identity promotes confusion we believe among consumers.

Consumers' expectations do not change when they cross state lines. Clear, simple, consistent national regulatory framework informed by risk-based science will enhance consumer trust not only in FDA, but the industry that you regulate. And we need these standardized products. It will also reduce frictions within the supply chain that are critical to our industry. FDA and other relevant agencies must provide this leadership.

We applaud and thank you for this public meeting as the next step in the stakeholder engagement process. We support this transparent regulatory process for stakeholder engagement including comment and rulemaking. This will ensure that all stakeholders have the opportunity to provide insights during the development of this really important regulatory framework.

We believe it's only with this type of process will -- transparent process will be effective and, more importantly, durable regulations be formed. We thank you for your time and welcome and questions should you have any.

MS. BARRETT: Great. Thank you so much. Next we have Anita MacMullen, North Carolina Department of Agriculture and Consumer Services.

MS. MACMULLEN: Good afternoon. My name is Anita MacMullen and I'm here on behalf of Joe Reardon, Assistant Commissioner for Consumer Protection with the North Carolina Department of Agriculture and Consumer

Services. Mr. Reardon could not be present today due to a pressing public health issue in our state. And I am presenting his comments for him.

On behalf of North Carolina we appreciate the opportunity to further speak about the misuse of milk Standard of Identity in regards to plant-based beverages. When FDA chooses not to enforce the law it erodes consumer trust in the agency and can endanger public health.

Milk has a clear definition and Standard of Identity established in regulation and FDA has a clear duty to enforce its Standard of Identity. Consumers expect and the law requires accurate labeling.

FDA has addressed the Standard of Identity for milk in warning letters sent at least three times since 2008 and we applaud them for the regulatory actions. Mislabeling is simply against the law.

The current trend towards enforcement discretion and inaction ironically comes at a time during which the market has exploded with more milk substitutes. Until recently, almond and soy beverages dominated this category. Now the market is quickly becoming more diverse with varieties such as oat, pea, cashew, rice, and countless other drinks virtually all labeled with the term "milk."

Many, many factures utilize the tactic of employing a compound word to circumvent the obligation to comply with the Standard of Identity. For example, using almond milk or oat milk as one word. Industry's still accountable for misbranding as such clever misuse of the term "milk" in a compound word deliberately aims to mislead consumers. If there's milk on the label, there should be milk in the product.

Standards of identity reflect consumer expectations and ensure consumers get what they pay for and understand what they feed their families. The plants used to create beverages vary broadly in their nutritional composition. There's a widespread misconception that such products are equal to or a viable, direct substitution for real milk.

This misguided assumption has a severe impact on our most precious and vulnerable population. As

recently as last week major news media outlets reported on recommendations from leading health organizations that included a warning that young children should avoid some plant-based beverages because they lack key nutrition vital for early development.

Consumers have long recognized the nutritional value of milk and the term is synonymous with whole, natural food, rich in calcium and protein. We are not advocating for the removal of these products from the market. We recognize that these products are a preferred, viable option for many consumers.

However, they should be labeled correctly without the term "milk" thus allowing consumers to make an informed and educated choice. Without truth in labeling it doesn't matter what's in the package. Consumer has the right to make informed choices and it starts with FDA protecting them from false or mislabeled -- misleading labels. Milk is clearly defined and so is FDA's role to enforce its Standard of Identity.

We do thank FDA for looking into Standards of identity and we appreciate the deliberative process that FDA's taking regarding modernizing Standards of identity. But in regard to milk the existing statutory and regulatory mandate is clear. We must move past providing comments and move into taking action.

We are disappointed that no action has been taken by FDA since the last public meeting on this topic in July of '18. We encourage FDA with the support of many others to enforce the Standard of Identity for milk and require proper labeling of plant-based beverages. It is imperative for public health protection.

North Carolina and other states stand ready and willing to assist FDA in enforcing the law. And in particular would be very interested in participating in the outreach that Doug Balentine mentioned this morning with state programs. I'd love to hear more about that and to be involved in the process. So please let us know who we can contact to initiate that dialog.

I thank you very much. We will be submitting our comments to the docket.

MS. BARRETT: All right. Thank you. Our next speaker is Patty Lovera, Food and Water Watch. And,

again, if you can say your name and affiliation.

MS. LOVERA: Hi. My name's Patty Lovera and I work with Food and Water Watch. We're and advocacy organization. So I just have a couple of points to make from our perspective about the issue of modernizing or changing Standards of identity.

Consumers don't use these in isolation. This came up in the last consumer breakout. You know, consumers are trying to navigate a very confusing marketplace. Standards of identity are one tool they have. They may not all use that tool. They may not all know about that tool, but some of them have it and consumers are desperate for tools for navigating this marketplace because it is very confusing.

And one way that we think about standards of identity that we've talked to folks about how they're using them is literally as a backstop for certain things that they are looking for. It might be something that is less processed, has a shorter ingredient list. And it is a more standardized item that they don't have to worry per se about what else might be in there.

So if there are changes to the standards of identity, there's a real key question there about how we're going to let people know what those changes are if they've become accustomed to looking for certain foods because they think they know what it means. It's going to be very important that it's not a surprise that you have to be on top of this kind of rulemaking process to know that there was a change.

The second point I wanted to make comes from our work on bigger food policy issues. I understand that this meetings about the nutrition improvements that could come from some changes and that that's the focus, but there are other impacts that happen when you change a standard, a supply chain changes to produce a food in a different way. And I'm just curious. I wanted to just make sure it wasn't lost that we're -- have a way to look at those other impacts.

I have talked to people in the last week who are dairy farmers who couldn't be here. And when they hear about ultra-filtered milk or changing the mix of milk proteins that can go into a standardized cheese they

have lots of thoughts about what that means in their supply chain and what it means for their milk price because these are drive -- these are economic drivers of supply chains and there are other players.

So if nutrition is the criteria, that's the criteria. But is there going to be an assessment of other impacts upstream possible in the supply chains and are we going to think about those supply chains? What if there is an ingredient that might make a nutrition improvement, but the only source is a really complicated supply chain that brings other risks?

We think risk comes with imported foods especially from some countries with different regulatory standards from ours. Is that a part of this equation and will that be considered?

And then finally the big question, right, we're all -- everywhere we go is kind of novel ingredients and new technologies whether it's plant based of, you know, cellular -- you know, cell-based -- I don't even know what to call it. We're still figuring that out. You know what I'm talking about.

And we've got to figure this out. And changing the standards of identity before we figured that out is going to be very complicated. The context we will throw in there that we are struggling with is the context of what else you all do at FDA.

And for consumers and advocates like us the grass process is not good enough. And so relying on the grass process to say this new ingredient that might have some nutritional benefit should go into the standardized food misses a lot of pieces for consumers who expect more than an industry self-determination that an ingredient is okay.

So I know that that's not how you framed this meeting today, but that's the context we think that this decision really needs to be evaluated at. So thank you.

MS. BARRETT: All right. Thank you very much for your remarks. Our next speaker is Cary Frye, International Dairy Foods Association.

MS. FRYE: Thank you. Good afternoon. I'm Cary Frye, Senior Vice President of Regulatory Affairs at International Dairy Foods Association, IDFA. A trade

association representing the nations dairy processors that supports three million jobs, that general $620 billion of economic impact.

Milk, yogurt, cheese, ice cream, and dairy companies are proud to manufacture and market a wide variety of safe, nutritious, affordable products that consumers enjoy; however, dairy products represent a third of the food standards of identity and these standards are significantly outdated and stand in the way of using new technologies, ingredients, and novel processes for dairy foods.

Dairy product manufacturers want the flexibility to meet consumer demands and produce more nutritious products. That is why we commend FDA for undertaking this meeting to consider approaches to modernizing food standards of identity.

The dairy industry has signed on to -- or submitted and signed on to numerous petitions requesting flexibility in the dairy standards. Some of these are still pending decades later(sic). Clearly a new approach is needed to allow dairy processers greater flexibility to create innovative, nutritious, and healthful products.

IDFA and our members believe that the horizontal approach to the food standards modernization is the best solution. We endorse the concept presented by the 2006 Citizens Petition submitted by the Grocery Manufacturer's Association, IDFA, and ten other food trade industry associations as the best path forward.

This petition included six categories of flexibility that can be applied on a horizontal basis to all food standards. These six principles would accommodate many of the changes the dairy industry is seeking in food standards modernization and I'll go through them.

Such as, one, the addition of ingredients added solely for technical, non-distinctive effects such as emulsifiers, stabilizers, preservatives, or the addition of mold inhibitors to all types of cheeses.

Two, the use of safe and suitable flavors and flavoring enhancers and safe and suitable ingredients such as, as we've talked about today, salt substitutes for lower sodium cheese and non-nutritive sweeteners to

make lower sugar flavored milks and yogurts.

Three, the use of advanced technologies that produce ingredients provided the finished food retains the essential characteristics of the standardized product. That would allow for the use of ultra-filtered and micro-filtered milks in cheese making and other dairy products.

Four, the use of alternative make procedures that are allowed in cheese to apply for all foods that would permit technologies other than pasteurization such as high-pressure processing to prevent spoilage in milk products.

Five would be the changes to basic shapes and six is improvements to nutritional properties that do not rise to the level of a defined nutrient content claim such as being able to increase protein on a gram basis rather than the required minimum 10 percent of the daily value.

Rather than petitioning for individual standards changes that take decades, food standards require and deserve clarity and certainty. That is why we fully support undertaking this holistic approach to updating food standards -- I'm sorry, to updating food standards that maintains the basic nature of the food while allowing for innovation.

In our view, the horizontal approach for standards would both benefit consumers and the industry. We look forward to providing more detailed comments to the docket. Thank you.

MS. BARRETT: Thank you very much. The next speaker Nichole Manu, the Good Food Institute. And if you'll say your name and affiliation, please.

MS. MANU: Good afternoon and thank you for the opportunity to speak today. My name is Nichole Manu and I'm a staff attorney at the Good Food Institute. GFI is a global non-profit working to build a sustainable, healthy, and just food system by supporting the markets for plant-based and cultivating the eggs and dairy.

GFI supports FDA's interest in modernizing standards of identity and specifically FDA's goal of promoting industry innovation and flexibility to encourage manufacturers to produce more healthful foods.

To that end, FDA should ensure that its horizontal approach to modernizing standards of identity will continue to allow plant-based dairy to use conventional dairy terms. FDA established several standards of identity including the standard identity for milk many decades ago to prevent fraud and economic adulteration.

Since then, producers have introduced thousands of new foods to market in response to consumer demand for innovative options including many new plant-based dairy options.

FDA should clarify that these new foods may reference standardized foods in their names as long as the food labels make clear that the product is distinct from the standardized food. Doing so is in line with FDA's Nutrition Innovation Strategy and FDA's historical practice.

For example, although bread has a specific standard of identity, FDA has allowed producers to label non-conforming products as, for example, gluten-free bread or flourless bread. These products are functionally similar to bread while presenting options for consumers who cannot or choose not to consume ingredients that according to the standard of identity must be present in bread.

Chocolate milk is a similar instructive example. FDA has acknowledged that because chocolate milk does not purport to be plain cow's milk it need not conform to the standard of identity for milk. The same reasoning should apply to plant-based dairy.

Plant-based dairy now counts for 13 percent of all retail milk sales and innovative producers continue to add new plant-based milks to the market to satisfy consumer demand. Ten years ago, soy and almond milks were often the only plant-based milk options available at mainstream supermarkets. Today it's becoming easier and easier for consumers to find oat, hemp, flax, pea, and other healthful plant-based milks at their local grocery stores.

It is clear that consumers are demanding these products not out of confusion, but because they are seeking out healthful, functional counterparts to cow's

milk products. Consumers buy these products specifically because they are made from the plant-based ingredient identified on the label.

Just as makers of gluten-free bread or rice noodles are not representing their products as standardized foods, plant-based milk producers are not representing their products as cow's milk. Rather names like soy milk or oat milk convey clearly to consumers that these products are functionally similar to cow's milk while made from different ingredients.

Just as consumers add cow's milk to their coffee or pour over cereal, they can do the same with soy, oat, hemp, and other plant-based milks. Allowing plant-based dairy producers to clearly and truthfully label their products is particularly critical for the 30 to 50 million American adults or fully 15 percent of the population who are lactose intolerant.

Allowing plant-based dairy producers to label their products clearly using terms and inform consumers as to both the content and functional characteristics of the product is consistent with FDA's goal of promoting innovation and flexibility to encourage the production of more healthful products.

We therefore request that FDA clarify that standards of identity do not prohibit the use of qualified standardized terms on plant-based dairy labels. Thank you again for the opportunity to speak today and we look forward to participating in the future.

MS. BARRETT: Thank you very much. Our next speaker is Douglas Hass with Lifeway Foods.

MR. HASS: Good afternoon. I'm Doug Hass, general counsel at Lifeway Foods. Founded by immigrants in 1986, Lifeway is the United States' leading supplier of the probiotic fermented dairy beverage known as Kefir.

Like others who have and will testify today, Lifeway's proud to manufacture and market a wide range of safe, nutritious, and affordable dairy and non-dairy products that meet consumer demands for innovative new products; however, the cultured milk standard of identity governing Lifeway Kefir is significant outdated and inflexible.

We commend the FDA for undertaking this meeting

to consider horizontal approaches, but that's not enough. Using Kefway Lifer -- Lifeway's flagship product, Kefir, as an example of the need for flexibility in food standards, Kefir's unlike other dairy products that you've heard about today.

Traditional dairy products do not contain the word milk along with a qualifier. The traditional name of Kefir or Lassi is simply Kefir or Lassi like Bordeaux or Brie. Traditional dairy products have a multibillion-dollar worldwide market, an established, flexible, legal definitions in the Codex, in the EU, and in their traditional home regions and countries.

U.S. consumers alone will buy more than 250 million cultured dairy beverages this year. But taking Kefir or Lassi as examples the current cultured milk standard of identity at 21 CFR 131.112 prohibits 1 percent milkfat Kefir or Lassi as being labeled as low fast Kefir or low fast Lassi, the traditional actual names of those foods used in every other country worldwide.

Instead Section 131.112 requires those products to be labeled as cultured low-fat milk, which they are not, or even more unwieldy and just as incorrect as Kefir-cultured low-fat milk or Lassi-cultured low-fat milk.

This inflexibility leads to perverse effects and I'm going to highlight two of them. First, Lifeway and other Kefir and traditional dairy manufacturers are forced to mislabel their products to comply with outdated regulations. Indeed, the FDA sent warning letters to two Lifeway competitors in 2017 requiring them to abandon using the traditional name of the food Kefir in favor of the incorrect, but regulatorily compliant phrase Kefir-cultured milk. That's shocking, but sadly correct. Traditional dairy manufacturers like Lifeway are compelled by the FDA to mislabel their products.

The United States is the only country in the world where Kefir or Lassi or Skyr or Villi are unlawful to sell by their traditional names. That does not promote honest and fair dealing as the FDA intends with its standards of identity.

Second and I think more importantly, non-dairy

cultured beverage manufacturers are free to mislabel their products as Kefir or Lassi with impunity. Unlike traditional dairy manufacturers that receive comment letters for using the traditional name Kefir, companies that wish to label a fermented coconut water or fermented tea or a kombucha as Kefir do so without fear of FDA enforcement actions.

Indeed, today Lifeway tracks nearly six dozen mislabeled products using non-dairy ingredients that utilize the name of the traditional dairy product Kefir in their labels or in their marketing. None of these products meet the agency's standard of identity for Kefir-cultured milk.

Perversely unlike anywhere else in the world, in the United States only, companies making non-dairy products can use the name the traditional -- of traditional dairy products like Kefir. It's, again, shocking, but sadly correct. Companies that do not make Kefir label their products as simply Kefir in the United States. They don't label is Kefir-cultured low-fat milk like Lifeway and other manufacturers do who must comply with the FDA standard.

Again, that does not promote honest and fair dealing. It sews confusion, it makes U.S. food labels outliers in the world, and most critically it invites and has created economic adulteration that harms consumers.

We would welcome a standard of identity for traditional dairy products like Kefir, but we recognize that this -- the reality that this kind of modernization may take years or decades and decades that consumers do not have.

It's overdue to produce some guidance on the traditional dairy food standards and we encourage the FDA to complete its work on the already drafted level-two guidance on traditional dairy products like Kefir and release it this calendar year.

Targeted guidance to solve obvious problems like these is just one part of the solution, of course, and we strongly encourage the FDA to look at alternative ways of providing flexibility and, again, in the coming months, not years and not decades. And to that end we also continue to endorse the broad concepts of the 2006

Citizen Petition submitted by GMA and IDFA that you just heard about.

Food manufacturers and consumers require and deserve regulatory clarity and certainty. We encourage a holistic approach to modernizing all food standards that maintains the basic nature of the food, enforcing the proper identification and naming of those foods, and allows for new product innovations and the introduction in the U.S. of ever more exciting foods from around the world.

In our view this approach of targeted guidance coupled with a broader, horizontal approach will greatly benefit consumers and the industry. And we look forward to providing more detailed written comments to the agency. Thank you.

MS. BARRETT: Okay. Thank you. Our next speaker is Mason Weeda.

MS. WEEDA: Good afternoon and thanks for having us here today. My name's Mason Weeda. I'm an attorney of OFW Law. I'm providing these comments on behalf of Bumble Bee Foods.

Bumble Bee Foods is the largest self-stable seafood company in North America and they offer a number of products that are subject to the canned seafood standards, namely canned tuna and canned Pacific salmon.

Bumble Bee appreciates FDA's ongoing nutrition innovation efforts, particularly the agency's attention to modernizing standards of identity, many of which have been around since the 1950s.

For its canned tuna and salmon products, Bumble Bee has needed to obtain temporary marketing permits to deviate from those standards so that it may innovate in order to meet consumers' changing needs and to address changes in manufacturing technology.

Bumble Bee strongly agrees with FDA that such horizontal approaches should not be implemented where the basic natural, essential characteristics, and nutritional integrity of such standardized foods are changed.

With this in mind, Bumble Bee has three specific suggestions on horizontal approaches, some of which we discussed today, and one general observation for FDA's consideration. The first approach could be applied

to many food standards by permitting more flexible flavor ingredients. Many standards are rigid and do not offer flexibility. For example, the canned tuna standard only permits the use of one flavor, lemon oil, which does not allow tuna manufacturers to adapt to consumers' changing tastes.

FDA should take a horizontal approach by permitting safe and suitable flavor ingredients in various standards. Such flexibility would allow manufacturers to provide innovative products that appeal to consumers' changing tastes. For example, a tuna with chipotle product could help increase fish consumption which is a recommendation that's made in the recent dietary guidelines for Americans.

Permitting safe and suitable ingredients also would enable manufacturers to offer canned tuna or salmon with ingredients like fish oil which would include the benefit of Omega-3 fatty acids contributing to the nutritional intake of consumers.

We also note that many of the relatively new or updated SOIs already permit safe and suitable ingredients and we believe this change should be implemented to the older food standards as well.

Our second and third horizontal approaches are specific to standards involving canned seafood, but they could also be applied to other canned standards. As a second approach FDA should permit safe and suitable packing medium in any style of pack provided the style of pack and packing medium are called out on the product label. Similar to permitting the use of safe and suitable ingredients, this would allow manufacturers with flexibility to create food that's capable of retaining consumer interest.

As a third approach, FDA should modernize the net contents method of measure and the declaration for canned products to align with international standards. This is needed due to changes in manufacturing technology. For example, the standards for canned tuna mandates a pressed cake weight test which was designed for old canning technology, three-piece cans. By modernizing the method of measure, we should include a drained weight measure which is consistent with the

current two-piece canning technology.

I've mentioned three possible horizontal approaches and we believe that FDA should consider that all three of these approaches have been adopted by the Codex commission, specifically the Codex standards for canned tuna and canned salmon. The commission as well as FDA has recognized the challenges in our global marketplace and understand that international harmonization could resolve not just challenges in the marketplace, but also alleviate burden on industry.

Therefore, we urge FDA to consider the adoption of Codex standards as a possible horizontal approach. Thank you.

MS. BARRETT: Thank you. Thank you for your comments. Our next speaker is Gabriel Wildgen, Harvard Law School, Animal Law and Policy.

MR. WILDGEN: Yes, hello. My name is Gabriel Wildgen. I am a student researcher with the Harvard Law School, Animal Law and Policy Clinic where some of our work focuses on the regulation and labeling of innovative foods. On behalf of my colleagues, I thank you for this opportunity to provide comments today.

We applaud FDA's interest in promoting flexible food innovation by modernizing standards of identity. I'll offer two recommendations today in support of this shared interest which we will elaborate on in a forthcoming written document.

First, the FDA should continue its longstanding practice of allowing food labels to refer to the names of standardized foods such as milk so long as the qualifying language such as almond or soy is included to make the products ingredients and intended use clear to consumers. Allowing this practice promotes innovation of healthier food products while also ensuring clear and truthful labeling.

The FDA originally established standards of identity to prevent fraud and to promote honesty and fair dealing in the food industry. This was years before the Nutrition Labeling Education Act required nutrition and ingredient information on food packages.

Today consumers can read nutrition facts and ingredient statements and choose the foods that best fit

their own preferences and needs. Consumers are not confused by product labels with modified names of standardized foods such as rice noodles, gluten-free bread, and almond butter.

When asked about plant-based milk, for example, consumer surveys have found that fewer than 10 percent of consumers actually believe that plant-based milks contain milk from cows. Consumers know full well what soy milk and almond milk mean.

Indeed, almond milk was invented in the 14th century in Egypt and has been an English term since the year 1390. And nearly half of consumers now regularly purchase plant-based milks along with dairy-based milks for a variety of reasons. These reasons include concerns about health, nutrition, environmental sustainability, and animal welfare.

In regards to health and nutrition, it must be noted that plant-based milks are as healthy or -- healthy or healthier than cow's milk. Dr. Walter Willett, the world's most cited public health expert, has made clear that humans do not need cow's milk to survive and thrive. Indeed, Canada's national food guide no longer even considers dairy to be a food group because it is so non-essential.

Further, the nutritional role of cow's milk can be filled by other products. For example, the 2015-2020 dietary guidelines for Americans includes fortified soy milk within the dairy category because it is -- because its nutritional profile is so similar and in some ways healthier than cow's milk.

Without reasonable public health or consumer confusion argument to justify restricting terms such as milk to only cow's milk or noodles, to only wheat noodles, the FDA does not have a legally substantial interest in doing so. This means that these appropriately qualified food labels are a form of commercial speech protected under the 1st Amendment.

This is why we strongly recommend that the FDA continue to allow this constitutionally protected speech. Indeed, courts should find that the FDA has no choice but to do otherwise.

Now to our second recommendation. The FDA

should publicly clarify that food producers may name and label their products using qualifying terms or phrases in front of standardized food names. The lack of such clarification has created uncertainty which could thwart innovation in food production thus limiting consumer choices for U.S. consumers.

By providing this clarification, FDA would lift any potential chilling effect on American food innovators and unleash their full creativity. In conclusion, the purpose of standards of identity is not to protect established industry from competition, but rather to protect consumers.

Regulations have not kept pace with modern innovation that is driving a more sustainable and healthy food system. The current standards of identity are inflexible and burdensome to change in response to new developments so this is why the FDA should maintain, but also clarify its current flexible approach to enforcing standards of identity.

This will encourage American food producers to innovate, improve consumers' choice, and increase the availability of nutritious, healthy, clearly-labeled foods. Flexibility, not enforcement of standards of identity is in the best interest of consumers and innovation. Thank you.

MS. BARRETT: Thank you for your remarks. Our next speaker is Mona Calvo.

MS. CALVO: Good afternoon. My name is Mona Calvo. I am a retired FDA expert regulatory review scientist. I'm currently a research adjunct professor --

MS. BARRETT: I'm just going to ask if you can just bring that down.

MS. CALVO: Bring it down?

MS. BARRETT: Yeah, perfect. Thank you.

MS. CALVO: I'm currently an adjunct research professor in the Icahn School of Medicine at Mount Sinai in New York City in the division of nephrology. My testimony relates to the goal of FDA's Nutrition Innovation Strategy which is to take a fresh look at what measures may be done to reduce preventable death and disease related to poor nutrition.

In my four minutes allotted I hope to present

compelling evidence for the need to make the new higher, lawful fortification levels of Vitamin D that can now be added to animal milks and yogurts and plant-based milk alternatives and yogurts mandatory rather than optional by requiring the new higher level of fortification as a component of the modernized standards of identity for these food categories.

Poor Vitamin D status from inadequate dietary intake negatively impacts bone health and immunity in elementary and secondary school students particularly in darker-skinned minority children and lower -- with lower skin synthesis of Vitamin D when sun exposure is adequate.

Excuse me, Vitamin D insufficiency and deficiency are linked to the increased incidents in severity of acute and chronic respiratory infections in school-aged children that include common cold viruses, upper and lower influenza and bacterial lung infections, allergic asthma, and otitis medium.

These health issues motivated us to study the Vitamin D intakes of school children in five two-year cycles of the continuous National Health and Nutrition Education Survey, NHANES, from 2007 to 2016, roughly over a decade.

We determined mean Vitamin D intakes of 6 to 11 and 12 to 19-year-old children and adolescents in three major racial ethnic groups -- non-Hispanic whites, non-Hispanic blacks, and Hispanics. Mean intakes over each of these five cycles for children 6 to 11 and adolescents 12 to 19 in all three major race ethnic groups were on average 5 micrograms of Vitamin D per day which is far below the estimated average requirement of 10 micrograms of Vitamin D per day. And were less than half the recommended dietary allowance of 15 micrograms per day with intakes in girls always lower than that of boys.

Using the extensive data gathered by the USDA's What We Eat in America, we determined that a large percent of Vitamin D intake was consumed away from home with approximately 75 percent consumed at breakfast and lunch. Recent use of Vitamin D fortified foods to improve intake and status in Canadian children suggests a feasible and viable strategy to improve Vitamin D intake

through school meal programs in the U.S.

However, such school meal programs need to provide adequate and acceptable Vitamin D rich food sources for elementary and secondary school students, but this is clearly not attainable through the few available products with optional or voluntary Vitamin D fortification.

FDA's 2016 changes in regulations governing the addition of Vitamin D to foods and the increase in the label intake guideline that now sets the daily value of 800 international units, that's 20 micrograms a day, will help to correct this problem only if fortification is mandatory and not left up to the discretion of manufacturers.

MS. BARRETT: Mona, I will ask if you can wrap up. Thank you.

MS. CALVO: Oh, if higher D fortification is made mandatory through the modernization of the standards of identity for both animal milk and plant-based milk alternatives and yogurts by requiring the higher addition of Vitamin D than the microgram -- the 5 microgram gap between Vitamin D intake and the estimated average Vitamin D requirement for school children and adolescents could be significantly reduced.

MS. BARRETT: Thank you very much for your comments. Our next speaker is Clay Detlefsen. Clay? National Milk Producers Federation.

MR. DETLEFSEN: Good afternoon. Thank you for today's meeting. My name is Clay Detlefsen. I work for the National Milk Producers Federation. Standards of Identity play an important role in guaranteeing that consumers' expectations are met in terms of key ingredients and sensory attributes.

National Milk supports FDA's desire to produce consumers with healthier foods and protecting consumers against economic adulteration; however, National Milk is confused. For decades plant-based dairy imitators have been marketing significantly nutritionally inferior products using dairy names in violation of FDA's rules and FDA has done nothing.

If FDA is truly interested in providing healthier foods and protecting consumers against economic

adulteration, FDA does not need to modernize standards of identity. They need to enforce the existing ones.

In comments filed earlier this year the American Academy of Pediatrics and the North American Society for Pediatric Gastroenterology advised FDA that they're aware of increasing cases of childhood malnutrition -- Kwashiorkor disease and Rickets -- that are occurring because consumers are being misled about the nutritional inferiority of plant-based substitutes.

Last week, as was referenced earlier, the nation's leading health organizations including the Academy of Nutrition and Dietetics, the American Academy of Pediatric Dentistry, the American Academy of Pediatrics, and the American Heart Association stated: "Plant-based non-dairy milks are not recommended as a full replacement for regular milk. Evidence indicates that with the exception of fortified soy milk many plant-based non-milk -- non-dairy milk alternatives lack key nutrients found in cow's milk. Even when these milks have extra nutrients added to them our bodies may not absorb those nutrients as well as they can from regular milk."

National Milk also takes issue with the notion of eliminating minimum milkfat requirements in standardized food. We see this proposed action is another way to cheapen food and lower their quality. Further, in many cases it's unnecessary.

For example, if a company wants to make a cheap version of ice cream with less than the 10 percent minimum milkfat, they can already do so. The product is called frozen dairy dessert. Eliminating the milkfat requirement will allow companies that make cheap, frozen dairy dessert to call them ice cream. Ice cream without cream, bizarre. How does that help consumers?

To be clear, if a company wants to use vegetable oil in place of some milkfat in a frozen dairy dessert, they have that option already. The product is called Mellorine. If a company wants to make mozzarella cheese with skim milk and vegetable oil, they can under 21 CFR 130-10(d)(2). That product would be imitation mozzarella cheese or mozzarella cheese substitute depending on the nutritional profile.

And I also want to point out that FDA does not have the authority to remove the milkfat requirement from butter because Congress wrote that standard of identity.

Finally, FDA stated that there are more than 280 standards of identity. 95 are for dairy products. Most dairy product standards are still relevant and don't need modification. Are we to alter all 95 because some may need some updating?

We also note that in the 80s FDA managed to modify 12 standards of identity for cheese to allow for the use of Antimycotic agents and did so in one fell swoop.

Grouping similar standards and modifying them as a group is therefore a proven means by which to accomplish any needed modification. So it could make sense to modify some standards -- cheese standards collectively -- but lumping dairy in with tuna and bread and other foods doesn't seem to make sense.

We support making healthier foods, but prefer standards be respected. And any changes that need to be made be made in a transparent manner that will protect consumers and preserve the integrity of our food supply. Thank you for your time.

MS. BARRETT: Thank you for your comments. Our next speaker is Michelle Simon, Plant-Based Foods Association.

MS. SIMON: Thank you. Good afternoon. My name is Michelle Simon. I'm the Executive Director of the Plant-Based Foods Association. PBFA was founded in 2016 to build a strong foundation for the plant-based foods industry to succeed and thrive. Today the association has grown to 160-member companies. We appreciate the opportunity to speak here today and join others in applauding FDA's goal in modernizing standards of identity.

American consumers are sophisticated and well-informed. Consumers purchase plant-based foods -- consumers who purchase plant-based foods are keenly aware of why they're making these choices and do so for many reasons -- sustainability, health, allergies, ethics, variety, and taste.

While grocery sales overall are flat, retail

sales of plant-based foods are growing quickly at a rate of 11 percent overall since last year. Therefore, we encourage FDA to support one of the few areas of growth within the food industry and one that is experiencing rapid innovation.

There's much discussion about the use of the word "milk" to identify plant-based alternatives. For our members and as the data shows for many consumers, the word simply describes the functionality of the product.

We are concerned about an overreliance on nutrition as the marker by which the application of standards of identity should be measured. Many consumers are seeking out plant-based milks and other animal alternatives to avoid certain components in milk and dairy such as saturated fat and cholesterol. In addition, many consumers cannot eat dairy due to allergies or intolerance. Approximately 65 percent of the population is lactose intolerant.

There's widespread agreement among nutrition experts that the nutrients in cow's milk products can be easily found in a variety of foods including plant-based alternatives. There's also mounting evidence that a proper diet based primarily on plant-based foods promotes optimal health.

We suggest that FDA take an approach that answers one basic question. Is the label truthful and non-misleading? Nutrition facts panel combined with the required statement of identity already provide ample information. Moreover, the free speech clause of the 1st Amendment protects companies that label their foods with truthful, non-misleading names.

To help ensure consistent labeling approach among our members, in 2017 PBFA convened a standards committee to establish voluntary standards for the labeling of plant-based milks. Last year we shared that finished document with FDA. We have also since required that all companies applying for PBFA's certified plant-based stamp adhere to those guidelines.

We are currently working with our members to create similar labeling standards for the plant-based yogurt category as well as for plant-based meats and plan to share those results by the end of this year.

This is the solution we believe is best for our industry -- flexible and inclusive. The FDA has the unique opportunity to support this growing industry and the millions of American consumers who are voting with their dollars.

Our members are committed to working with FDA and look forward to finding a solution to this important issue. Thank you.

MS. BARRETT: Thank you. Our next speaker is Steven Gendel or Gendel, Food Chemicals Codex.

MR. GENDEL: Hello. How are y'all doing?

MS. BARRETT: Good.

MR. GENDEL: A long day, right? So I'm Steve Gendel and I'm the Senior Director for Food Science at the Food Chemicals Codex. The FCC, which is published by the U.S. Pharmacopeia, is the largest independent source of standards for food substances. And we appreciate the opportunity to discuss modernizing standards of identity and the use of the horizontal approach for modernization.

SOI play a critical role in protecting the integrity of the food supply. The August 29th Federal Register notice that announced this meeting, and as we heard this morning, FDA began establishing SOIs shortly after the passage of the FD&C Act in 1938 to promote honesty and fair dealing in the interest of consumers. The FR notice also says that a primary agency priority is to protect consumers against economic adulteration.

Similarly, the Codex alimentarius says that food standards in general are established to protect consumers and to ensure fair practices in the food trade. When considering modernization of SOI it is important that we protect what consumers have gained from the current standards.

In addition, standards are foundational for supply chain transparency allowing for accurate communication from primary producers to consumers around the world. To quote Deputy Commissioner Yiannas, "Transparency leads to greater accountability and incentivizes every stakeholder in the food system to do the right thing every time."

Preserving the clear link between product names and compositions is provided by SOI is essential for

effective communication when supply chains are long and complex involving ingredients from many sources that undergo multiple treatments in different steps.

The FCC was created by FDA and the National Academy of Medicine and has served as a repository for public standards for food substances for more than 50 years. The FCC contains standards developed through an open, transparent process with participation from academy -- academia, industry, and government volunteers. Standard development includes an opportunity for and consideration of open public comment on draft standards and all comments are considered in preparing final standards.

The current edition of the FCC contains more than 1,250 standards over 200 of which are cited by referenced in FDA regulations. FCC standards are used by industry and governments internationally and are explicitly recognized in the laws and regulations in many other countries.

This is important because over the past 50 years the content of the FCC has changed in response to industry innovation such as the introduction of new types of ingredients, evolving production methods, and new analytical technologies. We've also actively participated in standard-setting processes such as at JECFA and AOAC.

We look forward to an opportunity to work with FDA and to offer our resources and expertise as a standard development organization and as a standard repository to help protect the integrity of the food supply. Thank you.

MS. BARRETT: Thank you. Our next speaker is Betsy Ward, USA Rice Federation.

MS. WARD: Hello. Thank you to FDA for allowing me to speak today on food standards of identity and modernization. My name is Betsy Ward. I'm with the USA Rice Federation. As a longstanding member of the rice industry, this is a topic that's near and dear to my heart. And I'm here representing our hard-working rice farmers and manufacturers in today's conversation about standards of identity.

As was just stated, the purpose of a standard

of identity as established in law is to promote honesty and fair dealing in the interest of the consumer. Food standards of identity are necessary to protect consumers against economic fraud as well as support the hard work of American farmers. So to help consumers make educated purchase decisions we recommend that a standard of identity be developed for rice.

Currently the only standard of identity that exists is for enriched rice. These standards provide a guideline for which milled rice can be fortified. And we do this to improve its nutritional profile and the standard also exists to protect against consumer deception.

Beyond this, rice falls under the common or usual name for non-standardized foods regulations which specifies that the name shall be uniform among all identical or similar products and may not be confusingly similar to that name of any other food that is reasonably encompassed within the same name. That's kind of a long definition.

The current use of a common or usual name, rice, has created confusion in the marketplace. Rice is a grain. It's not a shape. As such, an identical or similar product would be a different variety of the rice grain, not a non-rice product.

For example, there are products on the shelf now called ripe rice, which is hard to say, or frozen cauliflower rice in the same sections as white, brown, and other varieties of U.S. ground rice. These products are made from pulse-based flours or vegetables.

Internationally rice does have a standard of definition under Codex as whole and broken kernels obtained from the species Oryza Sativa. Furthermore, wild rice are four species of grasses from the genus Zizania.

So we recommend that these guidelines we adapted into formal standards of identity in the United States to meet consumer expectations from a nutritional and culinary standpoint as well as to allow for innovation.

We support new product innovation and use of pulse-based flours to create new and innovative products.

It's not our goal to limit such product development, but to ensure that all products are clearly labeled and not deceptive.

For instance, vegetables that have gone through the culinary process of being riced remain vegetables and should be identified using the verb form e.g. riced cauliflower. In addition, products that resemble rice in shape but do not contain any of the rice grain should be labeled differently so as not to consume -- to confuse consumers.

Defining a standard of identity for rice will ensure that consumers who purchase rice based on its nutritional profile are not deceived by products advertised with similar names. Cauliflower as well as pulse-based flower products do not have a comparable nutritional profile to rice and should not be marketed as a healthier alternative. Both are healthy, but fit different essential nutrient categories.

Additionally, whole grains including rice are a key recommendation in the 2015-2020 dietary guidelines for Americans. Rice grains are nutrient rich and supply energy, complex carbohydrates, protein, fiber, antioxidants, and more than 15 vitamins and minerals.

Establishment of a standard of identity for rice will provide additional benefits beyond the underlying statutory purpose of preventing economic deception. Specifically, this would promote greater opportunities for nutritious rice-based innovation.

In providing a standard of identity for rice we are ensuring that consumers remain protected when they purchase new products labeled as rice. They can be sure the product they purchase meets their expectations.

We think a standard of identity will allow for the development of new nutritious rice-based products, spark innovation, and meet consumer expectations. Thanks again for the opportunity to present. Thank you.

MS. BARRETT: Thank you. Our next speaker is Adam Friedlander, the Food Marketing Institute.

MR. FRIEDLANDER: Good afternoon. My name is Adam Friedlander and I'm a food safety scientist with the Food Marketing Institute, the trade association that represents and advocates on behalf of the food retail

industry.

FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies with close to 5 million workers and combined annual sales volume of 800 billion U.S. dollars. Our stores carry on average over 33,000 products with around 17 percent of total sales coming from private brand products.

FMI appreciates the opportunity to come out on FDA's horizontal approaches to food standards of identity modernization designed to give interested persons, including our membership, the opportunity to discuss FDA's efforts to modernize standards of identity as it relates to the thousands of stock keeping units offer in our member stores.

We plan to provide more detailed written comments, but wanted to offer FDA with some initial insights. We would like to begin by briefly mentioning that FMI and our members share the goals discussed in FDA's January 2018 strategic policy.

Particularly relevant to updating the SOIs our FDA's focus on FD -- on efforts to empower consumers to make better and more informed decisions about their diets and emphasis on fostering the development of healthier food options.

Consumers continue to look to food retail as an ally in supporting their health and food retailers have continued to develop new and innovative ways to assist consumers in meeting these goals. In fact, as noted in the FMI Speaks 2019 report, 37 percent of retailers surveyed offer nutrition programs and 30 percent employed retail dieticians to help consumers navigate the health and wellness space.

Although these nutrition programs, dieticians, and other offerings are designed to help consumers make healthier food choices, it is also extremely important that the 33,000 SKUs sold in our stores are labeled so that consumers fully understand their food selections.

In particular, food retailers often represent the last line of communication between consumers and their foods choices so transparency and clarity in labeling are extremely important to help consumers and customers select food items that contribute to a healthy

diet.

Whether we are discussing new standards or modifying existing ones, SOIs remain important to helping consumers understand product selections and warrant additional review and clarity.

FMI recognizes that efforts to modernize SOIs under the current framework post certain risks to innovation as notice and comment rulemaking can proceed at a slower pace than the development and demand for new product offerings.

We also recognize that many SOIs are out of date and may already conflict with consumer understanding of the products they're buying. Although FMI believes that modernizing SOIs is important for consumer clarity, any modifications whether through a horizontal or vertical approach must be reflective of consumer understanding and expectations.

Referencing the example of setting permitted variations within SOIs discussed in FDA's notice of the public meeting we would want to be sure that any deviation from the recognized standard does not affect consumer understanding of food safety or health and wellness goals.

Again, food retailers serve as a direct line of communication between consumers and their food choices, so it is extremely important that food labels be clear and easy to understand as consumers make important nutrition, food safety, and purchasing decisions.

On behalf of our members, thank you again for the opportunity to comment on this important subject matter and thank you for your considerations.

MS. BARRETT: Thank you for your comments. Allison Rivera, National Cattlemen's Beef Association.

MS. RIVERA: Hello. My name is Allison Rivera. I am the Executive Director of Government Affairs for the National Cattlemen's Beef Association. National Cattlemen's Beef Association is the nation's oldest and largest national trade association for U.S. cattle producers. On behalf of NCBA and our nation's beef producers, thank you for the opportunity to share our perspectives regarding the Food and Drug Administration's efforts to modernize food standards of identity.

Under the Federal Meat Inspection Act the U.S. Department of Agriculture's Food Safety Inspection Service is granted sole regulatory oversight of meat products. Before reaching the end, consumer beef undergoes a rigorous inspection process and all beef product labels are subject to a mandatory pre-approval process which guarantees the factual accuracy of those labels.

As such, beef has a reputation among consumers as being safe -- a safe, healthy, and wholesome choice of protein. Plant-based protein products mimicking beef, or what we at NCBA often refer to as fake meat, on the other hand are not held to the same set of standards be it food safety or labeling oversight.

These products health and nutritional values are not congruent with beef products, but by using the term "beef" and other terminology traditionally associated with meat food products consumers are led to believe fake meat is held to a similar set of standards.

Our most recent research indicates that of the consumers who are purchasing alternative protein products, 56 percent believe these products are nutritionally superior. NCBA is concerned with fake meat products which are marketed, packaged, and displayed in a way that trades on the good name, solid nutritional profile, and sound environmental record of U.S. grown beef.

Further, a number of plant-based fake meat products are now positioning themselves as a more healthful form of beef. Some of these product labels use terms like "beefy," "veggie beef," or "just like beef," while others make implied claims not backed by science in an attempt to position their products as superior in the marketplace.

For example, the Beyond Meat websites states that there is a 16 percent increased cancer risk and 21 percent increased heart disease risk associated with animal-based meats. A graphic on their website combines these two percentages for a total of 37 percent under a broad improving human health category. The reference accompanying this graphic is to a report published by the *Archives of Internal Medicine*.

It's unclear whether the company is implying consumers are 37 percent more at risk by consuming animal-based proteins or if consumers will be 37 percent healthier by purchasing their plant-based alternatives.

What is clear, however, is that *JAMA Internal Medicine* which took over *Archives of Internal Medicine* has no record of any publication under the title listed on their website. And without the author, publication date, or any other identifying information it would appear Beyond Meat's priority is to grow their market share through misleading communication efforts rather than providing customer -- sorry, consumers with enough transparent, science-based information to make informed purchasing decisions.

The overwhelming body of scientific evidence shows that beef is an authentic source of high-quality protein without a long list of ingredients and no added sodium. For example, a 4 ounce serving of 93 percent lean ground beef raw has ten essential nutrients at 10 percent or higher than the respected daily values per serving including high-quality protein, zinc, iron, and B vitamins at about 170 calories providing overall fewer calories, fat, saturated fat, and sodium and more protein compared to the majority of meat alternatives on the market.

Further, USDA consumption data shows that Americans are on average consuming only 1.7 ounces of beef per day. This intake is consistent with the 2015 dietary guidelines' recommendations as well as the recommendations of major health organizations worldwide.

As FDA considers horizontal approaches to SOI modernization, NCBA respectfully requests FDA initiate meaningful enforcement proceedings for improperly labeled imitation meat and beef products. Additionally, as new dietary trends emerge, we believe it is in the best interest of consumers for FDA to consider establishing new definitions and setting strict parameters around use of terms like "plant based." Thank you.

MS. BARRETT: Thank you for your comments. Our next speaker is Michelle Smolarski, International Food Additives Council.

MS. SMOLARSKI: Good afternoon. My name is

Michelle Smolarski and I'm representing the International Food Additives Council, an association of manufacturers and end users of food additives and grass ingredients.

IFAC supports that the FDA's efforts to modernize standards of identity in a way that reflects the current food environment supports industry innovation and meets consumer expectations. We would like to comment on three general principles we believe are critical to consider when modernizing standards of identity.

IFAC supports a holistic horizontal approach to modernizing standards to allow -- modernizing standards of identity to allow food manufacturers to use multiple food additives or related new technologies without affecting the basic nature and essential characteristics of standardized foods.

With that said, as a first principle IFAC strongly supports protecting consumers against economic adulteration and ensuring that consumer expectations align with the provided names of products. Any revised or new standards of identity should continue to guarantee the consistent delivery of quality and integrity originally intended by FDA's longstanding food standards.

Recognizing FDA's original intent to develop standards of identity for many products that are given a common name by which the product is generally known by consumers, it is important to consider the current and future food landscape which may include new products with common names now known to consumers but lack and need reliable defined standards.

Secondly, IFAC believes there is a tremendous opportunity to pursue standards modernization in tandem with supporting modern public health objectives. According to the most recent edition of the dietary guidelines for Americans, nutrients of public health concern now include potassium and Vitamin D in addition to iron and calcium.

Applying a horizontal approach to modernizing standards of identity and allowing for food additives and/or grass ingredients that improve the nutritional profiles of foods can shift -- can support shifts in eating patterns and help individuals meet critical

nutrient needs.

For example, allowing for potassium phosphate in place of sodium phosphate in baked goods and other products would increase potassium intake while lowering sodium levels, a nutrient FDA recommends consumers limit.

Lastly, we believe there should be no restriction on the use of or -- on the use of other authorized food additives and/or grass ingredients in standardized foods when the technical functionality is equivalent to food additives currently permitted.

To meet current consumer preferences the food industry continues to seek and develop new safe and alternative food additives, grass ingredients, and technologies. Restrictive standards of identity limit the ability of food manufacturers to take advantage of advances in science and technology to meet consumer demand.

For example, the current standards of identity for yogurt, low fat yogurt, and non-fat yogurt do not explicitly allow for the use of other bacterial cultures. Providing clear allowance for the flexible use of food additives and grass ingredients that impart the same technical functions such as fermentation, emulsification, and stabilization is critical to driving future innovation.

In closing, IFAC reiterates its strong support for applying a holistic horizontal approach to modernizing standards of identity that allows for the use of food additives to provide the same technical effects and consistent quality consumers expect from products commonly consumed. This will allow industry to deliver more innovative, healthier foods and beverages.

IFAC thanks FDA for the opportunity to provide comments and will submit detailed written comments to the meeting docket. Thank you.

MS. BARRETT: Thank you. Our next speaker is Ron Tanner, Specialty Food Association.

MR. TANNER: Good afternoon. My name is Ron Tanner. I'm the Vice President of Education, Government and Industry Relations for the Specialty Food Association. I'd like to thank the FDA for the opportunity to present the viewpoints of the specialty

food industry at today's hearing.

This Specialty Food Association is the trade association for all segments of the specialty food industry. The 3,800-plus SFA members -- mostly small and very small food manufacturers, importers, distributers, and retailers -- make and handle food products that are often referred to as "value added."

Specialty food sales in the U.S. are $148 billion annually according to research from Intel International. Specialty foods represents 16 percent of all food sales at retail and are growing at a rate three times faster than mass market foods.

More than 80 percent of SFA members are makers, the creators of innovative and healthy foods -- mostly healthy foods. We estimate that our members make more than 240,000 unique food products ranging from Virginia ham to California olive oil to Wisconsin cheese to kale chips from Texas.

The Specialty Food Association is uniquely positioned to offer feedback on modernizing standards of identity. We have many members who make food in the traditional manner conforming to the long-established standards of identity both in the U.S. and abroad; however, SFA members are also the innovators in food and many are pushing the boundaries in product consumption, flavor, packaging, and technology. For these companies the standards of identity are often a hindrance to bringing their innovative products to market.

As you read through the standards of identity the need for modernization is obvious. Products such as French dressing, deviled ham, Chop Suey, chicken Kiev, and chow mein without noodles harken back to consumer pantries in the 1960s. And who could possibly imagine that here were rules governing the manufacturer of Scrapple which I thought you could just throw anything in, but I learned different when I read the standards.

Today there's boundless innovation in the food industry. Just look at the bottled water category, the third fastest growing category in specialty foods. FDA describes bottled water as water that's intended for human consumption and sealed in bottles or other containers with no added ingredients except that it main

contain a safe and suitable antimicrobial agent.

Yet water today may include rosemary, lemon, honey, acai, vitamins, and even added oxygen. These products are labeled as water and are in violation of FDA's standards of identity.

The fruit butter category is another with standards of identity that limit innovation. SFA members make pumpkin butter, blueberry butter, cashew apple butter, and even granola butter. These innovative and healthful products are made by well-intentioned specialty food makers some of whom are small farmers producing value-added products to keep their family farms afloat. They do not want to violate FDA regulations, but the strict standards of identity are either limiting their creativity or putting them in non-compliance.

Creativity is inspiring foods that taste better and are often more healthy. Technology is contributing as some typical ingredients in products such a mayonnaise are being replaced by vegetable-based alternatives.

SFA urges FDA to stress clarity and simplicity around allowable names and terms and to use simple language when reworking the standards of identity. Many food makers today are entrepreneurs with family recipes, not food scientists. Simple language will foster innovation in food and help consumers choose products that they consider to be healthy.

We request that FDA act with a sense of urgency to avoid lawsuits around false advertising and unfair competitive claims as well as to provide clarity to consumers. And FDA should also take into its thinking that the advancement in nutritional ingredient labeling that is implemented over the past 25 years addresses many consumer issues that gave birth to the standards of identity.

We encourage FDA to have an ongoing review of standards of identity issues as the food industry is changes more rapidly than it has in the past.

MS. BARRETT: Okay. Thank you very much. Our next commenter is Lisa Weddig from National Fisheries Institutes.

MS. WEDDIG: Thank you. My name is Lisa Weddig. I'm the Vice President of Regulatory and

Technical Affairs with the National Fisheries Institute or known as NFI. NFI has been the nation's leading advocacy organization for the seafood industry for over 70 years. Our members range from harvesters, processers, importers, distributors, all the way to retail and food service operations.

Maintaining consumer confidence in seafood products through the safety, quality, and integrity of seafood products is a top priority of our membership. While there are only a handful of SOIs related to seafood products, we support the efforts of the agency to streamline the modernization process because maintaining the integrity of SOIs goes hand in hand with maintaining the integrity of seafood and food in general.

We appreciate the agency is considering flexibility in or expansion of allowed ingredients and flavorings in the concept of innovation. This goes beyond the initial perception that innovation is solely related to the use of new technologies to produce the allowed ingredients or the production of the standardized food itself.

Allowing for the use of any safe and suitable ingredient or flavoring will open the doors for a greater variety of products which can still meet the essential characteristics of standardized foods. For example, the canned tuna and shrimp SOIs currently allows for only a single flavoring, that being lemon. This obviously restricts innovative product development that strives to be adaptive to consumers' changing palates.

When many of the SOIs were originally implemented the disclosure of full ingredient statements was not required so there was a need to limit ingredients to those that consumers would reasonably expect to be in the products. Now that ingredient labeling is mandatory there is no need for such a restriction.

For the standards related to seafood products allowing a more flexible use of flavorings and/or ingredients does not necessarily improve the healthfulness of an already healthful product; however, this flexibility will expand the variety of these nutritious options for American consumers.

A more flexible standard of identity that

allows seafood processors to offer products and flavors preferred by consumers would help consumers meet federal recommendations to increase seafood consumption.

While most Americans eat plenty of protein foods in general, nearly all eat far too little seafood. The average American eats one serving and the average pregnant woman eats a half a serving of fish per week.

The report of the 2015 dietary guidelines advisory committee continues the dietary guidelines strong recommendations that American consumers strive to eat a variety of seafood two times a week.

We cannot leave without commenting about existing petitions to amend specific standardized foods. As you know, some SOIs have unique requirements that will not fit neatly into a horizontal approach to modernization.

The standard identity for canned tuna, for example, contains an outdated procedure for defining the standard to fill a container. Moving from the archaic press cake weight test to the drain weight test provides a method that is more accurate, easier for the consumer to understand, allows for regulatory oversight and enforcement, and is internationally accepted.

This correlates with the agency's goal of providing the consumer with accurate information about standardized products. We are encouraged that the agency is not abandoning work on existing Citizen Petitions for the sake of adopting horizontal approach to SOI modernization.

There is definitely a keen interest in our member companies as well as others for FDA to complete the revisions to the canned tuna SOI. Thank you.

MS. BARRETT: Thank you for your comments. Our next speaker is Seth Mailhot, Husch Blackwell, LLP. Seth?

Okay. We'll move on. Kyra Lindemann, Upfield U.S., Inc. Thank you.

MS. LINDEMANN: Hi. Thanks for the opportunity to speak to you today. My name is Kyra Lindemann and I'm here on behalf of Upfield U.S. As a global plant-based food company, Upfield is the number one producer of plant-based spreads with more than 60 brands with iconic

brands such as I Can't Believe It's Not Butter and Country Crock.

We're focused on delivering plant-based products that are great tasting and have superior quality. And we seek to deliver on our mission to create a better plant-based future.

At a time when consumers demand natural healthy foods that are sustainably sourced, Upfield believes consumers are best served by product names that are instantly recognizable. Upfield applauds the FDA's horizontal approach to modernizing standards of identity.

One such approach would allow manufacturers to use qualifiers along with common and usual names of foods as long as the product is labeled clearly. For example, plant or an equivalent term would be used to describe plant alternatives to dairy products such as plant butter, soy milk, or plant cream cheese. This practice is compliant with current law and the FDA is wise to formulize -- or formalize this approach as these practices are widely accepted in the market.

We recommend that the FDA recognize the terms historically used to describe foods that are understood by consumers. These terms describe the foods form and function and are words that are used in everyday life such as milk, butter, and sausage.

Recent research supports this recommendation as well. In 2018 the International Food Information Council published their findings concluding that three-quarters of Americans understand that plant-based milk products do not contain cow's milk. Consumers have likewise expressed awareness about products labeled as butter.

By adding descriptors to common and usual food names this approach would help support the FDA's Nutrition Innovation Strategy by maintaining the basic nature and nutritional integrity of both standardized foods and new foods that are made using plant and by allowing industry flexibility for innovation to produce healthier foods.

Additionally, Upfield believes foods that use the term "plant" in the name such as plant butter should be 100 percent plant-based with no dairy or other animal ingredients. We recommend that this requirement be

adopted.

Furthermore, standards of identity should never be used as a shield that prevents consumers from being fully informed. The introduction of the Nutrition Facts Panel provides consumers with important information; yet, not all standards require every ingredient to be disclosed.

For example, U.S. butter regulations permit the use of colors without declaring them in the ingredients list. Therefore, in the spirit of honesty and fair dealing in the interest of consumers we believe this needs to be addressed.

We agree with the FDA that the consumer perspective is critical. These changes to the standards of identity are an opportunity for the FDA to introduce horizontal equity across all foods.

To conclude, the current standards of identity of an outdated set of regulations. They were a product of a food system that today no longer exists. We applaud the FDA's efforts to evolve the standards to reflect consumers' choices namely to use functionality and consumer expectations to identify food products.

Thank you for your time on behalf of Upfield and we look forward to sharing a more exhaustive submission later in the fall.

MS. BARRETT: Great. Thank you very much. Our next commenter is Diane Welland, Juice Products Association.

MS. WELLAND: Okay. My name is Diane Welland and I'm a registered dietician and nutrition communications manager for the Juice Products Association, JPA. Thank you for the opportunity to provide oral comments. JPA will submit detailed written comments prior to the November 12th deadline.

JPA's a trade association whose international membership consists of major processors, growers, packers, brokers, and distributors of a wide variety of 100 percent fruit and vegetable juices, juice beverages, and drinks. Our members represent a significant majority of the juice and juice beverage processors in the United States.

JPA supports the FDA's standards modernization

initiative. In comments JPA submitted to the FDA in October 2018 pertaining to the agency's multiyear nutrition innovation strategy, JPA noted its support for a 2006 Citizen Petition cosigned by 12 food industry associations including JPA requesting that 21 Code of Federal Regulation, CFR, Part 130 be amended to develop a horizontal regulation to modernize the food standards and provide added flexibility in six areas.

These areas are, one, safe and suitable ingredients used solely for technical purpose; two, safe and suitable flavors, salt substitutes, sweeteners, and vegetable fats and oils; three, alternative manufacturing processes for ingredients; four, alternate manufacturing processes for finished products; five, changes in form and shape; and six, improvements to nutritional profiles.

A horizontal approach would provide more flexibility, increase innovation for standards, and have become out -- and have -- for standards that have become outdated and allow use of new technological advances. For example, some standards permit the addition of nutritive sweeteners only. Expanding the scope of the optional ingredients to allow the addition of non-nutritive sweeteners would aid in furthering the goal of decreasing the level of added sugars in foods.

The FDA's regulations permit standardized foods to be modified as a measure to improve the nutritional profile through use of nutrient content claims; however, nutrient content claims can also limit flexibility. For example, the regulations allow reduced calorie nutrient content claim provided the calories in the standardized food are reduced at least 25 percent compared to the reference food; however, even a moderate reduction in calories -- for example, 12 percent -- could help in achieving better dietary patterns.

We recommend that standards with nutrient reductions that do not meet the level of a nutrient content claim be permitted to convey information that is not false or misleading to the consumer through labeling statements. The reduction could improve the nutrient profile of the food supply and provide consumers with more healthful choices.

JPA supports a horizontal approach to

modernizing food standards, but also recognizes that there may be circumstances in which revisions to specific standards of identity may be warranted. The current standards for juices developed between 1977 and 1983 are outdated and tend to prohibit product innovation.

Since development of these standards' consumer preferences have changed, product technologies have evolved, and new ingredients have been introduced in the market. The current juice standards restrict the use of certain ingredients and thus limit the industry's flexibility to develop modified juices that may be called 100 percent juice.

Some of the standards do not permit the use of non-nutritive sweeteners, enzyme, and other processing technologies. The standards impose minimum Brix levels and as such restrict flexibility in the production of juices such as efforts to reduce the sugars content.

JPA welcomes the opportunity to engage with FDA on standards modernization. Thank you.

MS. BARRETT: Thank you. Our next speaker is Peter Goggi, Tea Council of USA.

MR. GOGGI: Good afternoon. My name is Peter Goggi, President of the Tea Association of USA, Incorporated, which was founded in 1899 to promote and protect the interests of the tea trade in the United States and as the recognized independent authority on tea. Our members span the full tea supply chain from growers to packers.

For decades we have studied and communicated the health benefits of true tea and want to work with the FDA to protect consumers and their expectations of tea when seeking foods and beverages that promote good health. I appreciate the opportunity to provide comment on the FDA's effort to modernize food standards of identity.

As mentioned in previous breakout sessions, standards of identity aid consumers in identifying and having confidence in the products they seek for taste, functional benefit, and/or specific unique needs that the consumer may have that are health related.

We recommend a formal standard of identity be established to ensure that only tea from the Camellia

Sinensis plant be considered tea. Tea from the Camellia Sinensis plant contains thousands of bioactive compounds including flavonoids that have been associated with cardiovascular, chemo preventive, cognitive health benefits and more. Tea from the Camellia Sinensis plant includes green, black, oolong, white, and dark teas.

Herbal teas, also called botanicals or tisanes, are not made from the Camellia Sinensis plant and therefore may not have the same well-documented health benefits as true teas.

Continuing to categorize herbal teas as tea may mislead consumers seeking the studied health benefits of tea. To preserve tea for green, black, oolong, white, and dark teas, herbal tea should be labeled according to their botanical such as ginger herbal tea or chamomile herbal tea.

All tea comes from the Camellia Sinensis plant, a warm-weather evergreen. True teas from Camellia Sinensis, as I said before, include black, green, white, oolong, and dark. And the resulting type of tea is based on how the fresh leaves of the tea plant are processed and their level of contact with oxygen. True tea is defined by being unrefined and in its pure state.

Herbal teas do not come from the Camellia Sinensis plant and instead are an infusion of leaves, roots, bark, seeds, or flowers of other plants. They lack many of the unique characteristics of tea and are not associated with the research on the potential health benefits of true teas.

We would request, therefore, that the FDA references these infusions by a clearly defined term separate from the standardized products green, black, oolong, white, and dark tea to avoid misleading consumers.

It is imperative to protect true teas essential characteristics from the Camellia Sinensis plant including its nutritional characteristics, health benefits. The bioactive compounds in tea may improve cognitive function and protect the brain cells from environmental damage.

Population studies have found that people who regularly consume three or more cups of black tea per day

have a reduced risk of heart disease and stroke. Studies also suggest that tea compounds have many mechanisms by which they may help reduce the risk of certain cancers.

Non-caloric tea consumption may aid in weight management by modifying metabolism through increasing energy expenditure and fat oxidation or improving insulin sensitivity. Tea consumption has been linked to higher bone density and improved muscle mass. Tea may support oral health due to its antibacterial properties and fluoride content. Tea may decrease the risk of kidney stone development.

By preserving the standard of identity for tea as products made from the Camellia Sinensis plant, we can still promote industry innovation to encourage manufacturers to incorporate tea into more products to contain the well-studied health benefits desired by consumers.

We appreciate the opportunity to explain the difference between two teas and herbal infusion products and why they should be classified with separate standards of identity. Thank you.

MS. BARRETT: Yes, thank you. Our next speaker is Joseph Profaci. I'm not sure if I'm saying that right, Joseph. It's the Northern American Olive Oil Association. So if you'll repeat your name and association, please.

MR. PROFACI: Yes, thank you. It's very close. Joseph Profaci.

MS. BARRETT: Okay.

MR. PROFACI: Thank you. So I am the Executive Director of the North American Olive Oil Association. Our members' products represent more than 50 percent of all olive oil sold in the United States.

The focus of today's public meeting, horizontal approaches to standards of identity, is especially relevant to the olive oil industry. But for olive oil the horizontal approach is needed not just to enable innovation, but primarily to provide consumers with needed protections afforded by technological advances and to provide industry with consistent and clear standards.

For many years our association has been advocating for a U.S. standard of identity. Our data

show consumers are confused over quality and types of olive oil and the terminology used for some products. And some disreputable merchants are taking advantage of that confusion and the lack of standards.

There are important differences in the health attributes among the different grades of olive oils and it's critical to give consumers the knowledge that the need to make choices for their health. An olive oil standard would help ensure that products meet consumers' nutritional expectations.

But it is equally critical that a U.S. olive oil standard not be static. Ongoing research continues to tighten standards and improve quality to protect consumers. This includes, but it's not limited, to the detection of economic deception.

As a result, the international standards on which most national olive oil standards are based are updated from time to time. A U.S. olive oil standard would need to have the flexibility to adopt improvements in standards and methods of analysis in order to assure American consumers have the protection of the latest scientific advances.

Unfortunately, FDA's existing statutory authority and the rulemaking process it uses to make revisions to standards of identity are costly and time consuming. So horizontal regulations can be the solution.

In 2005 the FDA, along with the Food Safety Inspection Service, announced the proposed rule which we've heard about multiple times today, to establish a set of general principles to revise the regulatory regime for food standards. And one of the objectives of those principles was to enable U.S. food standards to harmonize with international standards whenever feasible.

With olive oil in accordance with current regulations the FDA could adopt the Codex alimentarius standard with such deviations as petitioners may justify. The Codex standard, however, includes over 40 individual physical chemical parameters for extra virgin olive oil alone.

What happens when technology is able to improve on one or more of those Codex parameters or the

methodology used to assess them? Unless the U.S. olive oil standard were to automatically update when the referenced international standard is updated this would require a new petition every time a parameter or methodology is updated creating a nightmare of serial revision petitions.

Therefore, the FD - the NAOOA, my association, recommends FDA consider either of two horizontal approaches for the adoption of international standards. First, to the extent legally possible horizontal regulations should permit the automatic adoption of updates to the referenced international standard and rely on Citizen Petitions only if industry or consumer stakeholders oppose the update; or as an alternative, when FDA adopts and international standard such as Codex by reference, it should do so while retaining the discretion within its enforcement authority to deviate from the standard in accordance with the specific agency guidance or some other mechanism.

The establishment of which would, A, be more efficient than rulemaking in terms of time and cost; B, could be informed by input from industry and other stakeholders; and C, provide industry with regulatory certainty while assuring American consumers benefit from them most up to date science.

In summation, the standard of identity for olive oil is needed to protect consumers today. But in order to continue to give consumers the greatest protection into the future we urge FDA to find a way through horizontal regulations or policies to facilitate revisions and updates through referenced international standards such as the Codex. Thank you.

MS. BARRETT: Yes. Thank you for your comments. Our next speaker is Maia Jack, American Beverage Association.

MS. JACK: Thank you for the opportunity to speak today. I am Dr. Maia Jack, Vice President of Scientific and Regulatory Affairs at the American Beverage Association, ABA. The ABE represents the non-alcoholic beverage industry which shares FDA's Nutrition Innovation Strategy goals to facilitate industry innovation towards healthier foods and empower consumers

with information they can use to make healthier choices.

We support the FDA's effort to modernize standards of identity, SOI, in light of marketing trends and the latest nutritional science. We appreciate the invitation to provide comments on opportunities to make changes across categories of SOIs or horizontal approach without diminishing the nutrient profile of the standardized food, but allowing for innovations and flexibility that can lead to the development of healthier options.

For transparency sake, appropriate consumer disclosure requirements would accompany the following three options all of which will be discussed more fully in written comments. First, FDA should allow the use of any safe and suitable ingredient that achieves the same function as the SOI-permitted ingredient.

For example, defoaming agents should be broadly permissible in pineapple juice manufacturing and not be limited to Dimethylpolysiloxane, the expressly permitted ingredient. Similarly, wherein SOI permits use of a nutritive sweetener as in standardized pineapple juice, FDA should also allow the use of any safe and suitable non-nutritive sweetener provided appropriate disclosures are made.

Second, under the current horizontal SOI nutrient content claim regulation certain deviations from the standardized food are permissible such as use of flavor enhancers in reduced sodium standardized foods or non-nutritive sweeteners in reduced sugar standardized juices.

Similar ingredient substitutions should also be permitted when meaningful incremental improvements to the nutritional profile are made but which do not meet the threshold for nutrient content claim. The collective gain in dietary sugar reductions even when incremental across product categories would help FDA achieve its goals and align with dietary guidelines.

Third, horizontal standards should acknowledge technological advancements in the manufacturing process provided the updated manufacturing methods do not materially change the inherent properties of the standardized food.

While some juice standards may specify preservation via heat, sterilization, refrigeration, or freezing, it is not clear whether an advanced processing technique such as cold press, high pressure processing would likewise be permitted.

Other opportunities such as lowering minimum Brix levels for juices consistent with international Codex standards would serve two objectives; one, afford flexibility relative to SOI and related labeling regulation compliance and, two, align with FDA's goal for nutritionally improved foods.

Furthermore, citrus screening is a serious impediment for juice producers and formulators who are trying to comply with juice SOIs and can't do so without mixing the lower Brix fruit with higher Brix fruits produced in non-infested areas. USDA continues to restrict interstate movement of certain plant material and products from quarantine areas covering most of southern United States.

Finally, although new products continue to be introduced into the marketplace, FDA should resist the notion to adopt additional SOIs for newer beverage types such as kombucha teas to allow for innovation. The ABA and its member companies are committed to providing consumers with transparent information about our beverages. We share the important public health goal of having consumers reduce the calories and dietary sugars including added sugars they get from foods and beverages.

More beverage options including lower sugar, 100 percent juices can help Americans balance their diet and achieve their individual health and nutritional needs. Thank you.

MS. BARRETT: Thank you very much. Our next speaker is Debra Miller, National Confectioner's Association.

MS. MILLER: Good afternoon. I'm Debra Miller. I'm from -- I'm the Senior Vice President for Scientific and Regulatory Affairs at the National Confectioner's Association or NCA. NCA thanks FDA and this panel for this opportunity to appear before you today.

NCA strongly supports the agency's proposal to undertake horizontal approaches to modernizing standards

of identity for foods. A few woods about NCA. We are the leading association representing the nearly $45 billion U.S. confectionary industry. Chocolate and candy are produced in all 50 states employing approximately 55,000 workers at nearly 1,300 facilities in the United States.

Consumers love the products that our member companies make. And our members, in turn, are committed to providing consumers with quality confectionary products in a way that is transparent and helpful for people to understand and also to appreciate the unique role that chocolate and candy plays in a happy, balanced lifestyle.

Standards of identity have been a long part of the confectionary manufacturing especially for chocolate making. CFR Part 163 includes standards for cocoa nibs, chocolate liquor, cocoa, and white milk and sweet chocolate.

Today's consumers are looking for more choices and innovations in the treats they choose, and they know how to find information about the products that they choose such as the Nutrition Facts Panel, statements of ingredients, and other information on product labeling.

However, in some instances standards of identity have become barriers to making nutritional and functional improvements that the consumers are seeking. As we've heard, in 2006 the Grocery Manufacturers Association submitted a Citizens Petition requesting FDA to modernize its standards of identity using the horizontal approach.

We agree with many of the points raised in the petition. GMA looked to 21 CFR 130.10 which allows food companies to deviate from standards of identity for the purpose of making nutrient content claims as a model for updating standards of identity in a horizontal, efficient way.

Like 130.10, GMA's petition leveraged the use of labeling disclosures to communicate truly relevant differences between the modified standard product and the historical recipes. We agree with GMA that 21 CFR 130.10 is an excellent precedent for establishing additional horizontal approaches to SOIs across product categories.

We further agree that this flexibility is critical to making nutritional improvements and leveraging new food and ingredient technologies while still maintaining that basic nature and essential characteristics of the food.

GMA proposed six areas of flexibility for SOIs and one is permitting the safe -- the use of safe and suitable ingredients such as salt substitutes and sweeteners when appropriate in a standardized food. NCA specifically supports permitting substitution for one sweetener specified in a standardized food for another safe, suitable sweetener without having to amend the standard or obtain approval of a temporary marketing permit.

More generally, NCA believes that the optional ingredients listings in several current standards have become an obstacle to creating more nutritious products given advancement in food and ingredient technologies.

For example, the optional ingredient limitations in the milk, sweet and white chocolate standards, effectively preclude manufacturers from using rare sugars such as allulose, fiber, and protein in place of the nutritive carbohydrate sweetener like sucrose, despite the fact that the use of these ingredients would improve the nutritional profile of the products.

So we urge the agency to consider a horizontal approach that addresses this, and similar barriers across all standards which have a limitation on optional ingredients.

Separate from horizontal approach is an example of the shortcomings with the current SOI process is an NCA member's longstanding TMP for ruby chocolate, an innovative new chocolate product. A horizontal rule that permitted modifications to existing standards for cocoa products would have seen a faster and less costly introduction of this product to American consumers.

As the agency considers these proposals, we also ask for the approval of ruby chocolates TMP as soon as possible. NCA thanks you for this opportunity to present our views and we will be submitting written comments.

MS. BARRETT: Thank you. And our last

commenter, Julian Heron.

MR. HERON: My name is Julian Heron, Tuttle Taylor and Heron. May it please the panel, I appreciate your time today and your patience in listening to all of this because the work you're undertaking is so important to revise and improve and update the standards of identity and the important work you do. Knowing that I'm the only person now standing between you and happy hour I'll be very brief.

Just a couple of quick points. Consider as you're doing your work the fact that the ultimate regulators are the consumers. They vote every day with their pocketbooks; do they want the product? or do they not want the product? And there's no way to fool them.

And also consider that today, unlike just yesterday, the communication ability from you as regulators or between consumers is instant and that didn't exist years ago. So now you can get whatever message you want out instantly.

As you're probably aware there's been a number of federal court decisions recently saying that consumers are not confused by the labeling on plant-based milks. And those are very intense cases and the result has been the same in each one of them. And that goes to the fact that labeling today makes it pretty clear to consumers exactly what it is they're purchasing.

It was very exciting to see just recently the Dairy Farmers of America, the biggest dairy coop in the United States maybe the world, I don't know, but certainly in the United States just came out with a new product that's labeled a blend of cow's milk and almond milk and they use almond milk on their label, dairy farmers.

I yield back the balance of my time. Thank you.

MS. BARRETT: Thank you for your comments and sincerely thank you to everyone who has commented today. It's been a great showing of interest in this subject matter and we just want to thank you all. And we also really want to encourage your comments, be as detailed as you can, provide examples, consider other viewpoints that you've heard today, you know, and submit them by November

12th. So thank you.

I'm going to call up now Megan Velez who's going to close us out with some wrap-up and some thoughts of what we've heard today.

Megan? And as a reminder, Megan is our Acting Director in our Office of Regulatory Programs.

MS. VELEZ: Regulations and Policy at CFSAN.

MS. BARRETT: Okay. I was close.

MS. VELEZ: Thank you. So thank you all so much. As Kari said, my name is Megan Velez. I am honored to be here today to do the wrap-up, but also keenly aware that now I am what is standing between you and the start of your weekend. So I'm going to channel my collegiate football coach father and say, "Let's hustle."

First I just want to start off by saying thank you. Thanks to those that are in the room that participated today in the breakout sessions, provided public comments, and also those that are joining on the webcast. We appreciate the engaging conversation, the clear thought and preparation that went into your comments today. And, again, this information really does help us move the ball forward, so thank you.

Also I want to take a minute to thank the FDA team. As Dr. Mayne mentioned this morning, putting together a meeting like this is a lot of work. And I want to give a special shout out to the group from FDA that really made today happen.

So in closing, I wanted to touch on four themes that, to me at least, came out from both the comments in the plenary session, the questions the panel received, and conversation during the breakout session that summarize what we heard here today.

I'm not going to go into a lot of detail on these because I think in the next slides we will, but really I think these were the four things that jumped out at me. One was diversity both in the products that are standardized and the stakeholder needs both in terms of consumer needs and also industry needs.

Second was flexibility and the need for greater flexibility by industry stakeholders as well as, you know, others involved in this process.

The third was engagement. The need for us to

continuously engage as we move forward on this. Again, these are very diverse viewpoints that are in the room today. We appreciate the robust discussion, but it is very clear that this is a group that wants to engage with us moving forward.

The fourth is transparency. And so we'll touch again on all of these in the next few slides.

So in the first breakout session that dealt with nu- -- actually, pardon me. I want to take a step back. Before I dive into the wrap-up I did want to take one moment to clarify something that I think a number of us have gotten questions about that came up during the plenary session Q&A.

As most of you know, FDA in September of 2018 issued a request for information that was entitled Use of the Names of Dairy Foods in the Labeling of Plant-Based Products.

We did want to clarify that while we view this work as part of the Nutrition Innovation Strategy because it supports our goal of empowering consumers with information to make informed purchasing decisions, we do view this work as separate from the topic of the meeting today. Which I did just want to clarify because that's why you didn’t see this in the breakout session materials that we pulled together and why it wasn't raised by FDA in today’s conversations.

I just wanted to clarify that because, again, I think we have received a few questions. So thank you.

So then to dive into the first breakout session which dealt with the role of nutrition in standards of identity. I've included four bullets up here that I think, again, do kind of capture some of the larger comments and the themes that kept coming up in the various breakout sessions that we had on this topic.

The first was the need to consider ingredients that have a variety of purposes in foods. And the nature of this conversation was while there is -- a greater flexibility is needed, we also need to recognize that some ingredients that may not alter the nutrition profile of a food in some way, these same ingredients might, for example, impact a foods technical effects or performance characteristics. And this something that we need to be

mindful of in moving forward.

The second topic was just really I think dealing with the diversity of consumer nutritional needs. You know, consumer nutrient needs and goals are as diverse as we are and so as we consider the role nutrition will play in our standards of identity modernization work we need to ensure that this diversity is taken into account.

Third I think was the recognition that there's a really complex interaction between the purpose of standards of identity, the public health goals that we're seeking to achieve under the nutrition innovation strategy, and the consumer perspective.

So the stakeholders that attended these various sessions focused on that FDA really needed to be mindful of this in moving forward and ensure, again, appropriate stakeholder engagement throughout the process to make sure that we strike the right balance in any changes that we make.

Lastly, the topic of unintended consequences came up in these sessions as something that FDA needed to be mindful of moving forward. So an example that was discussed was if, you know, FDA were to change standards of identity to require new nutrients or additional nutrients in certain products we must make sure that we take that into account in terms of the whole -- the total diet.

The second session on industry innovation -- so, again, tell you about kind of the four key themes that emerged during the two sessions we had to discuss this topic. The first was really identifying that the pace of innovation in the marketplace and the consumer demand for new and innovative products is ever increasing.

Participants shared that FDA needs to explore a regulatory framework that is both broad enough to accommodate what is currently on the market, but also the things that we haven't even thought of yet moving forward.

The second was the need -- again, kind of building on that theme -- for FDA to develop a nimble regulatory framework that would allow us to shift quickly

to address new issues and react to a changing marketplace and consumer demands.

Going along with that was the recognition that while this flexibility is needed, it's important that consumers still recognize the standardized products subject to SOI. In other words, making sure that there are appropriate guardrails in place to do this.

And I think next was just the recognition in terms of ingredients, that with new flexibility may come technical challenges. And so this needs to be thought through in any horizontal changes that we make.

The topic of substitution was also brought up a lot, particularly with respect to ingredients or processes, but in the ingredients space a lot of stakeholders flagged for us that this isn't a simple one-to-one exchange.

As discussed in the previous slide regarding the nutrition wrap-up, there might be impacts associated with ingredient substitution that FDA needs to consider as part of this modernization effort.

The last breakout session and one that I was fortunate to be able to help co-facilitate discussed consumer expectations with respect to standardized foods.

So diversity came up in every session in pretty much every question that we posed. One I think there's just a recognition there's no one size fits all when it comes to consumer expectations about standardized foods. There are different groups, some discussed during the sessions were children, populations with allergies, or those who select or choose to avoid certain products or ingredients for health reasons. These individuals all have different needs and this needs to be taken into account as we move forward.

The second, again, was the issue of transparency. So participants in these breakout sessions noted that it's important that consumers know about changes to standardized foods. And this is something that all stakeholders should work together with.

A lot of good research was brought up during the sessions to highlight things going on in academia or with the various research groups and that's something

that participants said FDA should leverage moving forward - especially as they think about how to communicate this information to consumers.

Next was stakeholder engagement. So during the consumer expectation breakout sessions participants shared a wide variety of very robust data sources that could help inform this effort. These were data sources from industry, from consumer groups, from public health organizations, academia, and as well as the federal government.

Stakeholders at these sessions shared that it's important for FDA to engage to ensure that any decisions made are based on the best available information.

The next topic in the consumer expectations piece really focused on the issue of consumer awareness versus consumer expectations. So I think in both breakout sessions there was general agreement that while consumers may not be aware that a regulatory standard exists for many foods, they do have expectations about those products.

These expectations can come from many sources. These might include the product's taste, the look, the feel, or the way the product is used. And FDA should take this into account moving forward.

Lastly, flexibility again came up in this session. While flexibility is important as we've previously stated, there's a broad range of consumers, with unique needs and preferences. So, again, while standards are important, many in these sessions felt that additional flexibility must address this diversity.

So in closing just wanted to -- again, I think we've heard this enough, but put a plug out for the public docket that is open. In your meeting folders there is this great one-pager on how to comment to a public docket. So I do encourage you to do that.

For those of you that offered public comments today, we encourage you to file a copy of those comments to the docket as well as anyone else who has an idea to share, a perspective to share, or data or information to help inform our next steps.

The docket closes on November 12th so please get your comments in before that time. And also just

wanted to, again, note that the materials from today, the opening remarks, presentations, and the meeting transcripts will all in the near future be posted on the public meeting website.

So thank you all again on behalf of FDA for your time, your attention, and your engagement today. And I hope everyone has a wonderful weekend.

(Whereupon, the proceeding concluded.)