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

HORIZONTAL APPROACHES TO FOOD STANDARDS OF IDENTITY MODERNIZATION

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Rockville, Maryland 20852

A P P E A R A N C E S

Conrad Choiniere
Director, Office of Analytics and Outreach (OAO), CFSAN, FDA

Beth Briczinski
Senior Science Advisor for Milk Safety, Office of Food Safety (OFS), CFSAN, FDA

Cary Frye
International Dairy Foods Association

Sarah Sorscher
Center for Science in the Public Interest

Emma Gregory
FoodMinds

Steven Gendel
Food Chemicals Codex

Krissana Sukhumparnich
Office of Agricultural Affairs, Royal Thai Embassy

Betsy Ward
USA Rice Federation

Debra Miller
National Confectioners Association

Kris Sollid
International Food Information Council

Andrea Justo
Mondelez International

April Kates
EAS Consulting Group

Mona Calvo
FDA/CFSAN (Retired)

Mark Olney
The Good Food Institute

C O N T E N T S

P R O C E E D I N G S

SIMULTANEOUS BREAKOUT SESSIONS BLOCK #2

ROLE OF NUTRITION IN STANDARDS OF IDENTITY MODERNIZATION

DR. CHOINIERE: -- just to keep us on track. But before we get started I'm going to ask you all a big favor and you're all going to hate me for this,[…] but I'm Conrad Choiniere. I'm the Director of the Office and Analytics and Outreach at the Center for Food Safety and Applied Nutrition.

I am facilitating this session with my counterpart.

DR. BRICZINSKI: Good afternoon. So my name is Beth Briczinski. I'm a Senior Science Advisor for Dairy at CFSAN as well.

DR. CHOINIERE: And we have two folks from our Office of Nutrition and Food Labeling, Terri Wenger as well as Margaret Hannah and Rick Vernon. And they work on the product evaluation -- sorry production evaluation labeling team in our Office of Nutrition.

So we don't really have time for everyone to introduce themselves. When you do get the mic and you want to say something or join the conversation we would like you to introduce yourself at that point. Just tell us your name and who you're here representing.

But so we have a sense of who's in the room, how many folks here come from a food manufacturing company? How about a trade organization? How about consultants to the food manufacturing or trade organizations? Consumers, consumer groups? Public health groups? Government? Got some government. And researchers and academia?

Did I miss any categories? All right. Good. So as I said, when you get the microphone we definitely want to encourage you to tell us who you are and where you're from.

In your packets you'll have the questions and topics that we're going to talk about today. As you can see, there's a lot of material that we need to cover in the next 60 minutes or so. But our goal today is to gather your thoughts and your ideas and concerns as they relate to horizontal standards and how these can be used

from the production of a nutritious and health -- a nutritious and healthful food supply for consumers.

Our goal today is -- well, we are not trying to seek consensus here. We welcome all and any ideas that you may have, but we do expect that we're going to find some areas where we don't all agree. But we'll -- we want to engage in respectful discussion about those topics where we do agree as well as where we don't. We want to promote an active dialog and share perspectives.

Just wanted to also make you aware that this session is being recorded and we will be -- this is also being webcast. So for those of you that are viewing this session from the comfort of your home or office, if you do not have a packet you can find the materials on the website for this meeting.

But we will -- because we are recording this we are going to need folks to speak in the microphone when you want to speak. So Beth and I will be walking around and trying to get some mics to you as quickly as possible so we can have a flow -- free-flowing discussion.

All right. So did --

DR. BRICZINSKI: And we're not here to answer questions.

DR. CHOINIERE: Oh, right. Another point we made last time we're not here to answer questions. We might provide some clarification here and there, but we're not really here to answer questions. We're really here to just hear your thoughts and what your concerns are and what questions you might have.

So before we dive in I'm assuming you all went through one of these sessions in the morning, but if there's any questions about how we're going to move forward? All right.

So I'm going to pass it onto Beth to read some of the first questions.

DR. BRICZINSKI: So we have four questions. So if you look in your packet or for those of you who are online look at the materials online, we have four questions we're going to go through.

What I would really love to get from you guys today is I want to have some discussion. So back and forth, sharing your ideas with each other. You know, if

someone's going to propose a change -- we're talking about horizontal standards. So do you agree with that change for your product, okay? Would it -- maybe there be an implication that we haven't thought of? We want to know the pros and the cons so let's hopefully talk about that and get some good dialog going, okay.

So our first question is do Standards of identity pose barriers to the production of nutritious foods? And then if yes, which specific standard or categories of Standards of identity and what are those barriers?

So if you could just talk about that I think that'll help set the stage for this session. Would anyone like to go first?

DR. CHOINIERE: All right. I know we all ate lunch and we're all digesting our...

MS. FRYE: Thank you. Cary Frye, International Dairy Foods Association. And, yes, we do think that the current Standards of identity, particularly looking at dairy products, are outdated and have some limitations for how we can make nutritious foods.

So I'll just preface that we certainly support a horizontal approach. And one of those would be to allow for different types of flavors, flavorings or things like salt substitutes or different sweeteners.

And if we look at the dairy standards, milk does not allow for non-nutritive sweeteners, yogurt specifically doesn't, ice cream does. So we have a number of sweetened dairy products that only allow for carbohydrate sweeteners.

Now we understand that through nutrient content claims you can still use a non-nutritive sweetener, but you have to be sure that you're meeting the nutrient content claim such as low calorie or no sugar added.

And that gives you limitations. You couldn't add just a little bit of non-nutritive sweetener or some to maybe make a 10 percent reduction or a 15 percent reduction. So the example we want to share has to do with the use of non-nutritive sweeteners and to apply that broadly so that you could make -- use that non-nutritive sweetener without meeting a nutrient content claim. Thank you.

DR. CHOINIERE: Any reactions to that or something to add to that one?

DR. BRICZINSKI: Or another example? Any other standards that you think might have a barrier?

DR. CHOINIERE: Yep.

MS. FRYE: I'm just sharing for background with the group, IDFA had petitioned for this and we realize that FDA considered the petition and it is still pending to -- for sweetened dairy products to allow for non-nutritive sweeteners.

But I must say there was confusion by the consumer groups that what this would do and there was confusion that it was an idea that we wanted to add non-nutritive sweeteners to unflavored milk or un- -- you know, products that aren't typically sweetened and that wasn't the dairy industry's intent at all.

The dairy industry wanted to substitute where carbohydrate sweeteners are used in a flavored milk or sweetened yogurt. And really particularly we also wanted to bring to consumers understanding that it would always be labeled in the ingredient statement if used.

So I know those were two things that we heard during the -- when the petition was first being considered in a very public manner. And so I think when we're looking at changes to standards we have to be aware of consumer perceptions, but also think where the regulations do provide transparency for the consumer to know what the ingredients are. Thank you.

DR. CHOINIERE: Does anyone want to add to that? We did hear a lot of that in the morning session about the flexibility to reduce sweeteners and how that interacts with out nutrient content claim regulations.

All right. How would -- is there something about the last commenter said that may have an adverse impact on either consumers or on other product categories if we were to take such an approach?

MS. SORSCHER: So this is Sarah Sorscher from Center for Science in the Public Interest. We are a consumer group. I don't know offhand whether we're involved in this petition.

I think one question we have when we're considering making nutrition improvements that are

unmoored from an FDA-approved nutrient content claim is how those changes will be messaged to consumers in the labeling. We wouldn't want, for example, like a lower sugar ice cream or a lower sugar chocolate that is marketed in a way that confuses people into thinking that the product has a substantial health benefit over regularly sweetened products when that benefit doesn't meet an FDA-approved claim. So that's a big concern for us in thinking about allowing nutrition improvements that are detached from FDA-approved nutrient content claims.

We also have some questions about what substitutes will be coming in. You know, the safe and suitable standard when originally envisioned it was intended to be pegged to FDA additives approval. And we know that there are many additives now on the market that were approved through secret grass and so they didn't get that mandatory government oversight that was meant to be built in as a safeguard to that process.

And also substitutes intended to provide a nutrition benefit may not al- -- may also have unintended consequences. So we've been really supportive of efforts to substitute potassium chloride for sodium chloride in the food supply. But as part of the process we've looked into what unintended affects there could be and one of them is that people with chronic kidney disease are supposed to avoid potassium.

And we've actually seen population models suggesting that the net benefit would be positive. That the reduced risks for people without chronic kidney disease would far outweigh the risks for people with chronic kidney disease. And also potassium is a required disclosure in the nutrient facts panel so people with chronic kidney disease would be able to identify and avoid high levels of potassium.

But that sort of case-by-case review isn't necessarily available for all of these changes. And if you're thinking about a company going in and deciding on an ad hoc basis what's an improvement and what's not, we have some concerns about those consequences as well in addition to messaging.

Also we think the market might not always be good at filtering out, you know, good changes versus bad

particularly with vitamins. I know one of the reasons why we have standards for enriched flour, for example, is that it could be hard for consumers to tell the difference between flour with Vitamin D, the sunshine vitamin, and enriched flour that has all of the different components that are identified as priorities by the agency.

And so allowing for these kind of micro changes and diversity maybe become confusing and create public health challenges because the market won't sort out what the best product is.

So those are sort of some of the considerations and what we've been thinking about as these changes are proposed.

DR. CHOINIERE: Great. Thank you.

DR. BRICZINSKI: Yeah. So thank you for that comment because I think that's a good segue into our second question. So I'm going to go ahead and -- we have one more?

DR. CHOINIERE: There was one -- you sure?

DR. BRICZINSKI: Okay. Sorry. So going to our second question has four parts. So I'm going to introduce that and we'll go through and we'll have some discussion around this.

So we are interested in exploring changes that could be made across categories of standardized foods to improve the nutrition or healthfulness of those foods. So please share your ideas for specific horizontal changes that would help FDA achieve its nutrition-related goals by answering the following.

So the first question: What specific change or changes could FDA make to existing Standard of Identity regulations to improve the healthfulness or nutrition of standardized foods?

Two, which standardized foods or food categories would be impacted by the change or changes? So not just the one that you're proposing it for but, again, where are some of the implications?

Three, how would the change improve the nutrition or healthfulness of the food?

And then four, what are appropriate limits to this flexibility -- and, Sarah, you started to touch on

some of that. What are some appropriate limits to this flexibility to ensure standardized foods continue to meet consumer expectations?

So with that we'll open it up. I think we're going to spend a considerable amount of time on this question so if you would like to --

DR. CHOINIERE: So were there any reactions to the last comment related to some of the potential unintended consequences or some of the other issues that Sarah raised?

MS. SORSCHER: I can say some positive things too.

DR. BRICZINSKI: Okay.

MS. SORSCHER: All right. So, you know, I guess in favor of making more changes to the standards we do have standards that aren't supportive of public health. We have standards that have minimums on ingredients that are essentially minimums on negative nutrients we want to avoid.

Like, there's milkfat minimums for a lot of the dairy products which are essentially minimums on saturated fat content. There's soluble solids minimums for juice which are essentially minimums on sugar content. And, you know, to the extent that we never want to see the government mandating unhealthy ingredients I think we would like you to take another look at those.

I think, you know, in addition to some of the considerations I raised previously around messaging, you know, it's also important to think about how the regulations interact with each other.

So for Brix, for example, the soluble solids minimums for juice, those also determine the percent juice declaration in all juice drinks including ones with a lot of added sugar. And we wouldn't want to see changes that would allow companies to, you know, falsely declare that they had more juice because they were adding watered down juice to their sugar sweetened beverage.

So I think what that speaks to is the need to FDA to do a form of case-by-case review. Even as you consider horizontal standards there needs to be specific detailed consideration of these public health questions that can arise when you consider each of these changes.

DR. BRICZINSKI: Any reaction from the group on that concept of removing some of the percentage composition requirements whether it's sugar or fat, anything like that? Any comments, thoughts?

MS. GREGORY: My name's Emma. I'm from FoodMinds. I'll give it to you next, Cary. I am wondering too from a culinary point of view what is expected of the products when people are making foods, their functionality in addition to their nutrient profile.

So, you know, I can think of -- I say this lovingly -- a couple of cheese snobs in my life that would be pretty upset if cheddar didn't taste like cheddar or it didn't have the right consistency of cheddar.

And so I'm not saying that that's my point of view, but the culinary implications of what changing the standards might do to the world of foodies out there is something to consider as well.

DR. BRICZINSKI: Okay. So let's capture that as performance characteristics, right? So that's the -- you want your cheese to melt, you know, a certain way if you're making something at home following a recipe or if you're a manufacturing using that ingredient in your product it has to -- what other categories or changes? Cary?

MS. FRYE: Cary Frye, International Dairy Foods Association. I'm not going to comment on cheese. We don't have a position yet on that related to minimum milkfats. But when you're considering that you also need to think about if you're making a relative nutrient content claim such as it's reduced this much more, you do have to have sort of a grounding starting point.

But at the same time the dairy industry is asking for changes related to the yogurt standards. And we're very happy to hear that the long-pending petition for yogurt standards modernization which doesn't even meet NLEA standards for low fat or non-fat is moving ahead.

And one of the things we have proposed is that rather than having minimum milkfats for yogurt that it be based on a total fat basis. And the reason being is as

consumers sort of taste for types of flavors have changed in yogurt where they want flavors like coconut or chocolate or nuts that have added fat.

There was this sort of no man's land that if you added those to the yogurt portion and you started with a low-fat yogurt that you would no longer be low-fat, but you wouldn't meet the regular minimum milkfat. So we had this -- we weren't sure what to call it.

And so our suggestion from the yogurt industry to FDA was that allow -- base it on total fat and then look at the final food. And if it's 3 grams or more it's yogurt, if it's less than 3 grams per serving it would be low-fat yogurt and less than a half a gram per serving it would be non-fat. So aligning with the nutrient content claims.

So in the yogurt category we have worked that through and it seems like a very reasonable approach to accommodate new consumer tastes and also what industry needs to make a product that is informing the consumer of what the fat level is.

So I think there are way (sic) forward and the industry very much appreciates thinking in that of how you can accommodate milkfat levels and still be very transparent to consumers. Thank you.

DR. CHOINIERE: Reactions? New ideas?

DR. BRICZINSKI: The after-lunch crowd. If you're looking for ideas to respond to something, if you look in your handout we do have -- although we do not endorse -- six proposals that have come to us. So if you're looking to maybe, you know, generate a couple of ideas if you want to take a look at that.

I would be really curious for your products that you're interested in which of these proposals would be a good idea that you would support? Which of these do you think we would need to put some -- go forward with some caution?

Just I'm curious to see what you guys would think.

DR. CHOINIERE: We can read them to you. So we have one that's permitting ingredient substation to improve nutritional profile of foods, another to permit enrichment to replace ingredients lost during processing,

permit fortification to add beneficial ingredients such as adding whole grains and fiber, permit nutrients at levels that do not meet the threshold in the relevant nutrient content claim regulation. I think we've heard a little bit of that already.

Eliminate requirements or minimum -- and/or minimums and current standards for salt, sugar, oil, and fat as well as permit changes to meet consumer dietary needs. For example, gluten-free versions of foods.

And as Beth said, these were provided to you for discussion points. These are not intended to be proposals that we endorse or -- but some that have been proposed to us and wanted to get some feedback from you all about how these might be either useful or potentially --

DR. BRICZINSKI: Not useful.

DR. CHOINIERE: -- not useful.

DR. BRICZINSKI: Pause. Okay. I'm going to consider you guys a captive audience which means I'm going to ask you more questions.

DR. CHOINIERE: Before she starts singing.

DR. BRICZINSKI: No. I'm not going to do that. We're not quite that desperate yet. We might be getting there. Okay. So let's all look at proposal number three, okay. So permit fortification to add beneficial ingredients such as whole grains and fiber to standardized foods.

So I'm going to ask you guys a question. I'm going to make you answer. How would you define a beneficial ingredient?

DR. CHOINIERE: How are you going to make them answer?

DR. BRICZINSKI: His hand wants to go up. I think -- I think -- do you want to answer? You're looking at me with a look on your face. All right.

MR. GENDEL: I'm sorry. My face always has looks on it. I think that that's an extremely difficult question because what's beneficial to one person could be deadly to another. So if you have a -- if you're gluten intolerant, you have wheat allergy, adding wheat fiber is not a beneficial effect.

So there's no single answer to that question.

It's something that has to be approached on a case-by-case basis.

DR. CHOINIERE: Can you identify your name and organization?

MR. GENDEL: I think so still. I'm Steve Gendel and I'm with the Food Chemicals Codex.

DR. CHOINIERE: Okay. Thanks.

UNKNOWN FEMALE: I'm not sure how you would define a beneficial ingredient. I mean, FDA has certain authorized claims like the healthy claim, for example, that, you know, are very more clear cut. But having -- kicking it to industry to define on an ad hoc basis I think every -- as you say, everyone has a different definition and maybe every company has a different definition of what's beneficial.

I think it's also important to keep in mind that sometimes you have a product where there's a standardized product that has a lot of that beneficial ingredient already and the product that you're fortifying might be competing with that product. So bread is -- bread and wheat products are a great example because there are standards for whole grain bread.

We're talking about adding some level of whole grain that's not 100 percent to a regular bread product or a regular macaroni/pasta product to encourage people who don't like the whole grain product to try the fortified product. And I think, you know, oftentimes it's probably better for them to just get the part that's already available.

I think one of the things FDA should think about is very clear messaging around that particularly for whole grains which I think everybody does identify as a beneficial ingredient. And having a really clear declaration of the percent whole grain versus refined grain if you're allowing fortifications of products that compete with the standardized product that's superior is really important.

MS. GREGORY: Emma from FoodMinds again. What I'm thinking through is the fact that only 200 products have -- or foods have standards. And so when you think about which -- what portion of the food supply are we effecting by thinking about these changes to the

standards and is -- not is that enough, but then what do we do about all the other foods as well.

And so it feels narrow at times and then that kind of gets to the question of for what -- why do some foods become standard versus others? And then that might help us understand why -- why we're asking some of these questions in the first place too. And I think that's coming from a partially place of naivety for me too is understanding how the other foods are treated.

Can we do all of these things, you know, to foods that are not standardized? And so why -- what about the standardization? And I know the answer partially to that question, but it just made me think more broadly about the implications of the questions that we're answering.

MS. SUKHUMPARNICH: Thank you. My name is Krissana Sukhumparnich and I'm the agriculture attaché at the Royal Thai Embassy. In Thailand, we're exporter of can tuna products and currently we have a lot of innovation to improve the nutrients and quality of the products.

And one thing that we're struggling is we have standard identify -- FDA issue Standard of Identity of canned tuna. And it's not supposed to be fortified with any nutrients, but currently we have products that call -- we enrich the tuna -- it's innovation -- with tuna bone calcium. And it's -- currently it's not approved yet because we have the Standard of Identity of can tuna.

But in the future consumers should have choices to have product that enrich with calcium. For certain age group that would be good like the elderly people or younger age. And I think the Standard of Identity should accommodate fortification for nutrients that derive from -- also from the fish itself. Yeah, thank you.

DR. CHOINIERE: So just out of curiosity, this product is currently being produced and marketed in other countries?

MS. SUKHUMPARNICH: Not yet.

DR. CHOINIERE: Not yet? Okay.

MS. SUKHUMPARNICH: Just R&D.

DR. CHOINIERE: Okay. Just R&D? Okay. So there's an example of a standard we were kind of looking

for in the first question, you know, a standard that exists that is kind of posing as a barrier for potential innovation in nutrient area.

Are there other -- you got another comment over there? Okay.

MS. WARD: Hi. I'm Betsy Ward. I work for the USA Rice Federation. And to the other speaker's point, as you modernize the Standards of identity what about the products of commodities that don't have a Standard of Identity right now?

And that's really a question for you guys I think because rice -- there is no Standard of Identity for rice and we're having problems in the marketplace with products that aren't rice that are calling themselves rice. And we don't have any -- there is an international Codex standard for rice.

But so I think there's probably a long list of products that want to establish a Standard of Identity and I just don't know what the process is within FDA as you modernize the current ones.

DR. CHOINIERE: Well, then, let me just follow up on I think your point. I know we're not here to answer questions, but I think we can do some clarifying.

I mean, what we have here are we do currently have food -- Standards of identity for certain foods. The process by doing that I think you'll need to contact someone in our Office of Nutrition and Food Labeling to explore.

But we would like -- we have a Nutrition Innovation Strategy that we're trying to pursue. And so and how -- but some of these standards we've heard from industry are preventing the types of innovations that we would like to see to help improve the nutrition of the U.S. consumer.

So with the existing standards that we have we're trying to suss out of you all, you know, which of the standards are the barriers here and what are the things that we can do to help alleviate those barriers?

So we've kind of touched on some of these. Let's just throw all the questions out there. Oh, we got some --

DR. BRICZINSKI: We've got two.

DR. CHOINIERE: Oh, we've got --

DR. BRICZINSKI: Two. Oh, my.

MS. MILLER: I know you're not here to answer questions -- this is Debra Miller from the National Confectioner's. But in the preceding session in this room was the innovation session and a number of -- I think there's a lot of crossover between what is available in flexibility for innovation. And many of those innovations are to increase the nutritional profile of products.

So I think -- I'm just wondering you guys will all be sharing notes I imagine. But I think I'm just hesitant. I don't want to say the same thing I said in front of the same group again which would be kind of to your questions.

But procedurally I just want to make sure that everybody will -- all things will be shared across, right?

DR. CHOINIERE: Everything's shared and there's no -- you're not penalized for saying something twice.

MS. MILLER: Okay.

DR. BRICZINSKI: We haven't heard it so go ahead.

DR. CHOINIERE: Yes. And there are -- there probably are different people in this room.

MS. MILLER: But nobody has a candy name this time so I can't -- I can't use that. We had Mr. Reese the last time so. But --

DR. CHOINIERE: Sorry our names aren't --

MS. MILLER: I know, right? It doesn't always work out, right? But just some of the things that I had mentioned about confectionary in the last session was flexibility around sweetener use because some -- you know, in a low moisture solid food like chocolate which has many standards just replacing a sweetener with another sweetener isn't always enough.

There's bulk, there's mass that needs to be taken up. So fibers and proteins and other ingredients and flexibility in allowing for that full sort of technological, you know, salve would be very helpful. So I just didn't want to be repetitive with the group.

DR. BRICZINSKI: No, no, please do.

MR. SOLLID: Hi. Kris Sollid, International Food Information Council. I had a question about fiber. You brought up proposal three and it's my understanding that FDA has recently added beneficial fibers to the definition of fiber. There's seven or eight of them that are -- can now be labeled as fiber.

And so while I'm naive so I don't understand the product formulation, I'd love to hear from some companies who make these things.

But why would that be a bad thing if you've identified these fibers as physiologically beneficial does it conflict with the Standard of Identity to add them to foods if they're providing a benefit to people? And could there be an example of when this would change something's Standard of Identity? I'm better with tangible examples.

DR. CHOINIERE: Do we have an example, Beth?

DR. BRICZINSKI: I don't have an example. So could you --

DR. CHOINIERE: So he's talking about proposal -- which proposal is it? Number --

MR. SOLLID: Number three.

DR. CHOINIERE: -- three where it's --

MR. SOLLID: Fortification to add beneficial ingredients.

DR. BRICZINSKI: Okay. So is your question about beneficial ingredients in general or are you talking fiber specifically?

MR. SOLLID: Yeah. Well, I'm just using that as the example because FDA has added those to the definition of dietary fiber, correct?

DR. BRICZINSKI: Okay. Right.

MR. SOLLID: So if you therefore add them to foods, then it changes the Standard of Identity? I'm just looking for an example where that would be a bad thing and who would not want that.

DR. BRICZINSKI: Oh, so I’m not sure --

DR. CHOINIERE: I think it's because our question was in these proposals, you know, is there something potentially harmful that could happen.

MR. SOLLID: If you add it to yogurt is it not yogurt anymore?

DR. BRICZINSKI: So if it's not one of the optional ingredients that you can add to that standardized food then, yes, it's outside the scope of the standard. So that's what we're asking is do we want to open that up to all beneficial ingredients? How do we decide what those beneficial ingredients are? What guiderails do I put in place?

In some cases I might add a beneficial ingredient that is then going to have a technical effect in that good that then I'm going to have to add something else to counter -- you know, to counteract that technical effect that I just added.

And so how do we put a framework in place to address all of that, okay? That's a question for you guys.

UNKNOWN FEMALE: Yeah. I mean, and also keep in mind that under the current framework you can do that. You just can't call it just yogurt. You have to modify the name. And I don't know if you could call it yogurt with fiber or not under the current frame, but maybe -- we're not going to ask you guys to provide legal advice at this meeting.

But I think the two concerns -- the public health concerns are mainly around how it gets messaged to consumers because a lot of these products are not great, healthy foods to begin with. Maybe yogurt sometimes depending on how much sugar is in it.

But chocolate, for example, you know, it would be great to have a healthier chocolate, but mostly likely people shouldn't be thinking of chocolate as a health food, right? So you don’t want a name that makes it seem like you've got all these vitamins and you've got all these beneficial ingredients in a product that really is a sometimes food.

So I think that's one of the big concerns we have around the nutrition benefits is just this question of how they're going to message them in a way that doesn't confuse them with approved nutrient content claims or allow them to compete with healthier foods.

DR. BRICZINSKI: So like the pep and vigor in the vita-donuts that we saw this morning.

MS. JUSTO: Yeah. This is Andrea Justo. I

work at Mondelez. And kind of to that point and I was thinking the same thing, the usage occasion. So, you know, you don't want to -- if it's a snack food like chocolate or a treat, you don't want to over fortify chocolate because that's not appropriate, right? We don't want to misconceive.

So that's what I was just thinking the same thing. I just wanted to add that. You'd have to kind of look at the consumer usage and if it's really appropriate so.

MS. GREGORY: So then to decide which foods we can and cannot add physiological beneficial ingredients then do we have to take the next step and start categorizing foods as sometimes foods, you know? Like, what does that imply if we're going to allow these additions to make?

And I guess that's a question for the room.

DR. BRICZINSKI: That's a question I was going to ask you guys.

UNKNOWN MALE: Just kind of related to that I just had a thought like how these things would modify ATI scores or some -- for that example to Emma's point. You start having to get very specific, but one of the ways we gauge the overall diet is by these types of metrics. So how does that come into play?

UNKNOWN FEMALE: So this discussion on fortification makes me wonder and ask the question and we support flexibility related to different fortifications and nutrients. But there is another overlying FDA regulation and that's FDA's fortification policy.

So would -- I guess it's something that would need to be considered if a horizontal approach was taken if changes were made then there's other regulations that would need to also be updated. So I just want to mention that.

DR. BRICZINSKI: Right. And I think that goes to our fourth question here about the appropriate limits to flexibility. So I think that would be something to consider.

Are there other limits or guardrails that you can think of that we need to consider as we're looking at these?

UNKNOWN FEMALE: Can you expand on that because FDA's fortification policy doesn't have a lot of clear lines right now, right? You know, the sort of advisory advice not to fortify junk food. And then to the extent it's enforceable it's only when you make a healthy claim or a more claim that they can really -- they really come down on that policy.

So do you think there's a way to make that the jelly bean roll a little clearer for industry?

UNKNOWN FEMALE: I'm just suggesting that because it's so ambiguous at times and because it's maybe unclear to the industry of what the status is of the fortication (sic) policy, it would need to be clarified related to this so it is clearer for consumers and for industry of where are the limits. So I think we're both on the same page.

MS. MILLER: So from -- just in terms of the Confectioner's perspective, I think we're -- our question would be what -- if we're going to define a beneficial ingredient, is a beneficial ingredient one that helps reduce sugar or other -- or saturated fat or something like that is that separate? Is -- you know, what category is that ingredient?

Certainly, you know, we understand the fortification policy as we don't always like to use its colloquial name that people use, but I think we need to think about, you know, how do we use ingredients for -- you know, to improve the nutritional profile in terms of reducing some ingredients that we'd like to see, you know, just less of in certain product categories and to take advantage of new technologies whenever possible.

DR. CHOINIERE: Yes. We heard a little bit of that this morning too with the -- you know, you might have ingredients that aren't nutritive per se, but they're in the foods for technical reason whether they be emulsifiers or preservatives that maybe contribute to sodium, for instance.

And if replacing them with another ingredient would that be a beneficial ingredient? I think that's what you're kind of getting at.

DR. BRICZINSKI: Sorry. We'll both go. All right. We're in sync. Sorry. There you go.

UNKNOWN FEMALE: I'm curious about any detail that people have about the consumers' ability to know when substitutes have been added to their food. Is it just by the ingredient line or there have been any companies that have started disclosing that in different kind of ways and does that bleed into another pillar of the innovation strategy which is ingredient label modernization? And how do those two things intersect?

DR. CHOINIERE: Anyone have any thoughts/response to that? Sarah?

MS. SORSCHER: I'm sorry. Feel free to cut me off. So there is for one of the existing horizontal rules that FDA has they allow you to change -- swap out ingredients in order to make an FDA-approved nutrient content claim.

So, for example, if you want to make a no sugar ketchup you can add sucralose instead of the nutritive sweetener that's optional under the standard, but you have to put a little asterisk by the ingredients list and say that this is an ingredient not normally found in ketchup.

So and I don't know exactly where we come down yet on that. I think it is important to message when an important change has been made especially if it has a public health implication. But you also don't want to over message on something that consumers may be didn't need to receive information on or could even be misleading if you're, you know, making essentially a health claim with that disclosure, yeah.

And it is weird. We had a consumer send in a complaint about ketchup. The label also said sweetened only with red ripe tomatoes so the sucralose was a little bit jarring for that reason as well, but it sticks out to folks when they see that asterisk. And people don't generally know why it's there and how it relates to food standards I think.

DR. CHOINIERE: We had one other question, right, related to --

DR. BRICZINSKI: We have questions three and four.

DR. CHOINIERE: Well, can you read them? I don't know if we're already hit on those at all, but...

DR. BRICZINSKI: Do you want me to go down here?

DR. CHOINIERE: Yeah. Why don't we?

DR. BRICZINSKI: Okay. So let's move onto question three. So are there existing food standards -- for example, those established by voluntary standard setting bodies or regulatory counterparts -- that would be an appropriate model for FDA to use in order to achieve our nutrition goals? And then tell me why.

MR. GENDEL: So I'm Steve Gendel from the FCC. And the answer is obviously, yes, there are. They're the ones that we do at the Food Chemicals Codex. There are JECFA and Codex alimentarius standards which have some force under international trade.

Why are they good? Well, for one thing because they can be done apparently a lot faster than FDA can. And we have a lot of -- at least in our case experience with being flexible and modernizing our standards as needed.

So I think there are other models that the agency can work with and I think there are other organizations that the agency can partner with to meet these goals that they have.

DR. CHOINIERE: That's a little bit different than what I heard in this morning's session.

MR. GENDEL: Then they were wrong.

DR. BRICZINSKI: Sure.

MR. GENDEL: Actually, to expand on that a little bit and there are -- for instance, back in the days when FDA did food additive petitions there were standards established for a number of food additives by citing other sources. In particular I think there's something like 200 of the food additive regulations which cite FCC standards.

So it has been done and the agency has done that in the past quite successfully.

DR. CHOINIERE: Yeah. One of the comments I heard this morning was that they felt that the Codex standards were also out of date.

MR. GENDEL: Codex alimentarius standards are, yes.

DR. CHOINIERE: Okay. Okay. All right. Any

others?

DR. BRICZINSKI: That's it?

DR. CHOINIERE: We didn't get a lot of takers this morning on that one either.

MS. BRICZISKI: Wow. Okay. So we'll move onto question four and then we're going to bounce around and see where we go. How can we make changes across categories of Standards of identity that would accommodate future advances in, for example, science and technology as they relate to improved nutrition to avoid the need for frequent Standard of Identity revision?

So I'm going to start with that and then I'm going to tell you some of the things that we heard this morning and I want to get your feedback. How can we make these evergreen?

DR. CHOINIERE: So to get to your point about how quickly it takes to make food standards or revise our food standards, if we're going to go in this process of putting in horizontal food standards how we do it in such a way that we're not here again in five years or three years given how quickly advances are being made in science and technology in the food sector?

UNKNOWN MALE: So I apologize, this is probably politically incorrect. But the discussions we've had here today point out that there are a lot of individual issues that effects particular standards, particular potential modifications and all of these things. And the issue that horizontal standards is intended to answer is not Standard of Identity or anything else. It's lack of resources and prioritization at FDA.

So given that, I'm not sure that there is an answer to keeping these things evergreen if it's not going to be raised to a level that there will be the resources necessary to deal with it.

MS. KATES: I don't know if this is worth the microphone or not, but there might be a way to have the standards have whatever the regulatory -- whatever is determined to be the regulatory core of each food standard be a regulation and then for certain other parts of the standard that might deal with things that can change over time and that would be TBD, right?

Could be perhaps done as guidances that are

maintained online as -- and the industry can go there and find out what the latest whatever is. I don't know because the trouble with guidance, of course, it doesn't have the force of regulation. But it's just a thought of kind of dividing the standards not by types of food, but by exactly what you're requiring and then what is optional.

Oh, April Kates. I used to be in the Product Evaluation Labeling Team. I used to be the Team Lead there in the Office of Food Labeling.

DR. CHOINIERE: Thanks.

DR. BRICZINSKI: So I'm going to go back to my question that I asked earlier when we were talking about beneficial nutrients. So how do you define a beneficial nutrient when the science is changing? What do we turn to? What could we as FDA look at for the authoritative source for beneficial nutrients?

UNKNOWN FEMALE: Well, my first thought goes to the dietary guidelines, of course, as something to consult. And then as Kris mentioned before, the Citizens Petitions that FDA reviewed and then released their consideration of what physiological beneficial dietary fiber is.

But I do know that took some time. And, you know, if we go through an FDA approval process to define what is considered a physiological benefit of nutrients how long would -- you know, would that -- maybe in the long run that would be efficient, but in the short term as we're all waiting for changes is that the most efficient way?

But dietary guidelines is what immediately comes to mind.

DR. CHOINIERE: Reactions?

DR. BRICZINSKI: So my reaction would be so if the dietary guidelines are going to change every five years, how do we make sure that we're always in alignment? So any thoughts on that?

DR. CHOINIERE: We got one back here.

MR. SOLLID: Hi. This is Kris from IFIC again. I was just curious if maybe -- I know the guidelines are looking at reports like the DRIs from the National Academies. Could they be synced up in a way that their

commissioned to review them every certain number of years or -- I'm not sure what that process is.

I know they just did sodium and potassium. I don't know why that happens or how often that happens, but possibly there's a broader or larger strategy that could be all pulled together.

MS. CALVO: Mona Calvo, ex-FDA. I'm currently a research professor at Mount Sinai School of Medicine. One of the things that we talked about this morning for the dietary guidelines is the fact that they always go through the current data to look at what is -- what nutrients are limited in our food supply in what people are consuming.

And I think that that's the major thing that you want to focus on. Not so much as to what the dietary guidelines recommendations are such as three glasses, two glasses of milk, but what nutrients are limited and what actions are -- is the agency taking in order to assure that the American public has food sources that can supply those particular limited shortfall nutrients.

Another thing that I think you can look at is the use of enhanced data which can tell you the status of a lot of these factors in foods of our population as it changes every two years or if you want to follow trends over decades and things.

So I think the data's there in other government agencies who maybe have more resources to go through the literature and the science that's there.

DR. CHOINIERE: All right. So we've had four -- was it four questions --

DR. BRICZINSKI: Mm-hmm.

DR. CHOINIERE: -- with a bunch of sub questions. Tried to go through them in order, but if there are any -- are there any thoughts that people have not yet shared that they wanted to share in this particular session whether it be related to any of the individual questions that we've already asked or some questions that we didn't ask and that you think we should be asking?

Okay. All right. So, well, we've heard a lot of some similar things across the board. We have a lot of notes. We're going to capture all of these and try to

summarize what we've heard today.

If you do have any other thoughts after leaving today we want you to share those thoughts with us. We have a docket that you can submit your comments to. I think Margaret has done a great job writing down the docket number on every sheet there in case you missed it.

And, of course, if you -- as I said, you're not penalized for saying things twice. So just because you shared it here at this public meeting you can also share it again in the docket itself.

So, Beth, do we want to try and capture some of the things --

DR. BRICZINSKI: Talk about some of the things we --

DR. CHOINIERE: -- top lying things?

DR. BRICZINSKI: Your angle's probably better to read than mine.

DR. CHOINIERE: Well, we heard a lot about some barriers in the dairy as well as in I think the confectioner -- confectionary products. We saw -- we heard a lot about how these -- what we're trying to do here in food standards is going to interact with the other parts of our Nutrition Innovation Strategy.

And, in fact, the three sessions that we had today -- although we tried to put them in compartments -- we have innovation, we have nutrition, and we have consumer expectation -- they really are all kind of related in some way. And that there is the potential for some unintended consequences whether it is related to how consumers might react to these products or the claims that are made about these products.

We have some discussion about how required minimums may be a barrier to improving nutrition here. We had a little bit of discussion about beneficial ingredients, how do we define beneficial ingredients. Some -- I do sense that there is some confusion probably among people about, well, the role of food standards -- why do we have some food standards for certain products and not for others and what can and you can't do as it relates to food standards and the claims that you make about these products?

Am I missing any big themes too?

DR. BRICZINSKI: Performance characteristics, we talked about that and how that plays a role going -- and that loops into the consumer expectation about how if you're going to make changes to a product consumers still expect it to behave or taste or perform in a certain way.

Let's see --

DR. CHOINIERE: And, again, there was also some discussion about specific ingredients --

DR. BRICZINSKI: Yeah.

DR. CHOINIERE: -- such as sugar, fat, some of the ingredients that are added for other reasons.

DR. BRICZINSKI: Constantly looping that back into how do you educate consumers and message to consumers, how was it labeled, what's a good way to share that information. Again, this is all about empowering consumers with information.

So, you know, not to do something because you're trying to modify a standard to hide particular ingredients. You want to be very transparent with consumers in that respect.

DR. CHOINIERE: So are there any concerns or thoughts in addition to what we've heard today that you want to share now before we come to a close?

DR. BRICZINSKI: Yes.

DR. CHOINIERE: Great.

MS. MILLER: Thank you. Debra from the Confectioner's Association. So I want to thank you guys for really looking at this issue closely. I think it's really important for, you know, the consuming public to trust the food supply and trust the folks who make it especially. And I think the standards really provide a lot of structure.

Obviously everything needs to move on, modernize and this is a big undertaking for you all. And I think, you know, the standards really at their heart give, you know, what is important that basic essence of the food that makes it that food. And that's really important to maintain.

And some of the flexibility, though, might be in the limitations on some optional ingredients and how do we construct those optional ingredients to include these beneficial either ingredients or nutrients and how

do we broaden that set of tools for manufacturers and consumers to, you know, either be able to consume products that are better nutritional profiles either with more nutrients or less of sugar, fat, or other things that they may be trying to reduce, calories included.

So this has been I think -- I know it's a tough process, but it's a really important issue. So I just want to thank you guys. And if we could think about sort of what is those bar- -- that basic essence that really makes a standardized food standardized and then look at the flexibility around that.

I don't know if that's a helpful framework or not, but that's the -- you know, what we've been hearing that would be helpful for at least our sector.

DR. CHOINIERE: Thanks.

DR. BRICZINSKI: Thank you. That's a really good comment which I'm trying to remember. I know at one point -- hold on. Let me see. At one point we were talking about putting -- I don't have the handout. Let me see.

We talked about putting a question in here. I don't know if it made it in here. But so she brings up something which we have the time so I'm going to throw it out to the group. How do you decide what the basic nature of a food is? How do you decide what the essential characteristics are?

UNKNOWN MALE: So is the definition food it's contributed to the taste, aroma, and nutritions. That's food. Otherwise it will be junk.

DR. CHOINIERE: But I think what we're getting at is for one of the standards for, say, well, milk -- I guess that would be a pretty basic standard. But for milk, what's the fundamental core of that standard that makes it milk and then around it can be flexible?

DR. BRICZINSKI: Right. So or I was going to say, you know, like so the confectioner example what is the basic nature of chocolate, right? I mean, sorry, we were talking *Seinfeld* earlier. "Mocolate," right, like or whatever that *Friends*, whatever that episode was, right. You don’t want mocolate, you want chocolate.

So what is the basic and essential characteristics? How do we go about defining that? And

once we know what that is then using that as the foundation to underscore, okay, this is what we can't touch. What else can we play with?

And I think that's what we're trying to get, you know, through this process is where can we make changes that are going to benefit nutrition without changing that foundation.

MS. SORSCHER: Yeah. So I don't know the answer to this for you guys. I know that when FDA took sort of horizontal changes approaches in the past one of the safeguard and guiderails that was put into that process was requiring that any ingredient that was mandated under the standard not change and any ingredient that was prohibited under the standard not be included.

So that's one way to look at it. I'll say, you know, these questions about taste and appearance and enjoyment are really hard to measure. I will say as a consumer certain Greek yogurts do not taste right. And, you know, there was probably a different process that went into that and they thought they were producing a product that would meet consumer expectations for Greek yogurt. It didn't meet my expectations. That scenario where we don't have a Standard of Identity.

But I think, you know, to the extent that right now a company can make an alternative product and innovate, make it nutritious, and sell it under a different name. If they want to use the standard name they're trying to take advantage of a consumer expectation there. They want to access that market and go with something that people are familiar with.

And I think we need to figure out how that's going to be respected if we're thinking about changes to the standards. So I don’t know if the answer is to do this mandatory ingredient, prohibited ingredient thing. I think for some of the cheeses and other foods process is also important.

So but, yeah, that's one approach that you all have taken in the past.

MR. OLNEY: Mark Olney with the Good Food Institute. And I think partially addressing that, I mean, if you look at how consumers understand the products, right, we talk about the performance or kind of

these functional characteristics, right, does it melt whenever you put it on the sandwich, you know, is it savory, is it sweet?

And I think that that's something that's really conveyed through a lot of standardized terms if you think about dairy, right? When you think about, you know, the difference between nut juice, right, and almond milk or almond juice, almond milk, you know, milk says creamy, right, and it says you put it in your coffee, you put it -- pour it over your cereal, et cetera. And so it says something to the consumer very deeply about the nature of this product, the basic nature of what we're asking about.

So I -- this is only a partial answer. This wouldn't apply to kind of all categories. But I think there are many foods that work like that. I mean, you think about bread, right? It's not essentially that it have the wheat in it because we can have the gluten free bread that functions in the way consumers essentially understand what bread is.

So I think it's important to think about how consumers are approaching these products, how it's functionally presented to them and how they use them. And especially, I mean, if we're going to talk about innovation in the food category, right, plant-based products are one of the biggest innovations happening right now.

So to -- you know, we can't avoid thinking about that particular category I think in this way in looking at the growing consumer demand for it and making sure that clearer terms are being able to be used. You know, you can call it milk, you can call it cheese. People are buying it because it's plant-based. Not confused that it's a diary product.

It has a nutritional profile that they're interested in getting.

MS. FRYE: Cary Frye, International Dairy Foods. I just want to respond to the comment on Greek yogurt. There's lots of different types of yogurt There's French-style yogurt, there's Greek yogurt, there's Aussie yogurt. All of those products have to meet the yogurt Standard of Identity. They are in

compliance.

Whether you prefer one type and how it's made those ingredients -- and the consumers will dictate obviously. One might like it this way, one might like it this -- a different way. But I want to be very clear that those products comply with the yogurt Standard of Identity.

MS. SORSCHER: Yeah. I meant only that there's not a standard for Greek yogurt specifically.

MS. FRYE: But it has to meet the yogurt standard, yes.

DR. BRICZINSKI: Okay. We still have ten minutes. I mean, we can talk. We can keep talking. We have the room. Like I said, you're a captive audience. We're captive moderators. We can't go any earlier than you can.

Anything else? Any other comments?

MS. SORSCHER: I should also say that CSPI takes no position as to whether there should be a standard for Greek yogurt. That was me speaking for myself as a consumer.

DR. CHOINIERE: Sarah will be following up with the manufacturer.

DR. BRICZINSKI: Any other comments? Okay. So if not, I would make a plea that you please do consider submitting written comments to the docket. It would be very helpful. Take what you've heard today, think about it, consider how it might affect your products in a good way, bad way. Specific suggestions are always great.

What else? Let's see, in terms of next steps so we're on break until 2:35 and then we have an open public comment period. Folks will be giving some public comment. After that Megan Velez will be coming back up here. She's going to do a wrap-up so summaries of all of the breakout sessions.

So if you didn't get to go to a breakout session and you want to hear some of the common themes that were said in those other sessions come back, make sure you're here, stay for that.

Otherwise I just want to thank you all for coming, taking the time, sharing your perspectives. It's incredibly helpful for us as staff to have this sort of

dialog so I do appreciate that. Thank you very much.

DR. CHOINIERE: Yes. Thank you, everybody.

DR. BRICZINSKI: Okay. Thanks.