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HORIZONTAL APPROACHES TO FOOD STANDARDS OF IDENTITY MODERNIZATION

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BREAKOUT SESSION - BLOCK #1
Role of Nutrition in Standards of Identity Modernization

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P R O C E E D I N G S

SIMULTANEOUS BREAKOUT SESSIONS BLOCK #1

ROLE OF NUTRITION IN STANDARDS OF IDENTITY MODERNIZATION

DR. CHOINIERE: So, why don't we get started. It's 10:30, and we've had a long break. I'm looking at the folks in the way extremes of the room because we have one wireless mic, and I'm going to be walking around trying to facilitate discussion. It may be easier if you guys could move in toward the center, and then that way you could participate in today's discussion.

All right. Let me introduce myself. I'm Conrad Choiniere. I'm the director of the Office of Analytics and Outreach, the Center for Food Safety and Applied Nutrition. I'm one of the facilitators today. Our other facilitator, I will have her introduce herself.

DR. BRICZINSKI: Hey, there, good morning. My name is Beth Briczinski. I am a senior science advisor at CFSAN, working in milk.

DR. CHOINIERE: And we also have two other folks from FDA, who are scribes. We have Margaret-Hannah Emerick Vernon, and Terri Wenger. They both are in our Food Labeling Standards staff in our Office of Nutrition and Food Labeling at FDA.

So, we're here to -- so, we don't have time to actually introduce all of you, but it might be a good idea for us to have a sense of who is in the room. So, I was wondering if you wouldn't mind maybe raising your hands if you are a member of industry or a food manufacturer? Great. How about if you're a representative of a consumer group or personal, or a private citizen? Good. Public health groups? We've got one. Other government? A few government. And maybe researchers or academia? We've got some of those. Any categories I may have missed? How would you categorize yourself?

SPEAKER: [Microphone inaccessible]

DR. CHOINIERE: So, you're kind of -- you're part of the private sector but you support the industry that would be affected with standards. Okay, compliance services, great. Industry associations, okay, great. Anybody else I missed? Great.

So, if you do participate in today's

discussion, when I give you the mic, I would ask that you introduce yourself and who specifically you are here representing today.

So, in your packets you should all have a list of the topics that we are going to talk about today. There's quite a few. I think there's four or five broad questions and several sub questions in those. We will be reading them out loud, so that if you don't have a packet then you won't be lost. But our goal today is really to gather your thoughts and ideas and concerns related to how horizontal standards could be used to promote the production and supply of more nutritious foods to consumers. And specifically, we would like to identify specific potential changes across categories of foods -- and I'll read it, I'm sorry -- to encourage production of more nutritious foods.

So, as I said, what we'll do is, I'm going to try and pass around the mic with each question and try and facilitate a discussion across. We're hoping that we can have not just input from individuals, but also some discussion across some of the individuals that are in this room. But we are not trying to seek consensus here. All ideas are welcome, and we do expect that we will have some areas where we don't all agree, and that's okay. Because what we're here -- FDA's goal is we're here to get those ideas so that we can have a better set of information that we can work with as we move forward in this area.

So, I'm going to promote some active dialogue to share your perspectives. Oh, and I do want to remind you that this session is being recorded, and we have a transcription service in the corner, so the recording is used to help us with transcription. So, we will want everyone to speak in the mic so that the recording captures your thoughts.

As Kari had mentioned, we're hoping we'll have some respectful engagement, but given the time constraints, we may need to cut off discussions to move on to -- so that we can make sure we cover all the questions. But we'll try our best not to cut off any really active discussions.

All right. So, that was it for my intro.

Before we begin, are there any questions that anyone wanted to ask about how this will work? All right, great. So, I'm going to -- we'll start with Beth maybe reading off our first question, and we'll get some input.

DR. BRICZINSKI: Okay. So, if you go to your packets for the nutrition breakout session, we're going to walk through these questions. Question No. 1. Do standards of identity pose barriers to the production of nutritious foods?

DR. CHOINIERE: And maybe we can do the sub question as well. So, if you think yes --

DR. BRICZINSKI: If you think yes, then tell us which specific standard or categories of standards and what are those barriers?

DR. CHOINIERE: So, who wants to kick off this discussion? All right.

DR. CALVO: Hi. I'm Mona Calvo. I'm retired CFSAN, and currently I'm a research adjunct professor at the Icahn School of Medicine in New York City. My question is, are there standards of identity for specific foods that are used for medical purposes? Not medical foods, but foods that are used for medical purposes, such as low sugar for diabetics, or low phosphorus for people with CKD, chronic kidney disease? And, also, if there are, are there ways that we could improve these across categories for this specific purpose?

DR. CHOINIERE: Okay. So, we're not really here to answer questions, but if there are thoughts on that issue, if there are foods that are used for medical purposes for which we might have standards, are there things that we can do to improve those standards?

DR. BRICZINSKI: Are there other standards? Okay, good, good.

MR. GOGGI: Sorry, I'm -- my name is Peter Goggi. I'm with the Tea Association, Tea Council of the USA. So, I think in my views and it kind of follows up on this question, it's almost a reverse question in the sense that sometimes it's the lack of the standard of identity that causes a problem. So, in the case of her question, it might be there are certain foods or something that don't have a standard of identity, so you don't know that it contains the healthful properties. In

my case, specifically for tea, we want to preserve the word "tea" for that material coming from *Camellia sinensis,* black, white, green, oolong, versus an herbal tea, because tea has very well known, very well researched healthful properties -- cardiovascular, anti-cancer, etc., etc., that other teas, because they're just bagged in a bucket of things called tea, the consumer may get confused because they're thinking they're getting those benefits and they're not. So, the lack of a standard of identity at times can actually cause a barrier and a point of confusion in the consumer's mind because they may be seeking specific health benefits or specific purposes out of the foods that they consume and they're not getting it because of an incorrect label or a lack of identity.

DR. CHOINIERE: Any reactions to that thought or to the previous comment?

MS. WU: Just to continue the conversation about tea. Our company actually captures the global for regulations, also for the beverage, so tea is part of the nonalcoholic beverage. But we have noticed some countries does specific the species of the tea in their regulation, but some country does not, like black tea, the green tea, they all coming from different species. From the regulatory point of view, if those species names should be included in the regulation to be more precise in order to make the standard of identity to be more clear to the consumer or not, that's probably, it's just one of my thoughts on this. Oh, my name is Phoebe Wu. I'm coming from the Verisk 3E Company. We are providing kind of food regulation compliance service database.

DR. CHOINIERE: All right. Any other thoughts about the lack of standards? I'd like to shift back to the idea of the horizontal standard idea, where we're working with the existing standards that we have, what changes might we want to make horizontally? And given the existing standards, are there specific ones where some of you feel that the current -- that there could be improvements made to allow for more nutritious production of those foods?

MS. CHEN: I think, based on the previous successful case of folic acid fortification into cereal

product, which successfully decreased the nutritional defect. So, based on this previous successful case, other nutrition fortifications such as vitamin D, other nutrition, can be also fortified to some kind of vehicle of food to increase the public health. And, of course, when we consider these kind of nutrition fortification, we should be very careful to those specific market center, like old people, seniors, or like cancer survivors. Yeah, those are my thought. I am Liwen Chen from Fonaly Consulting.

DR. JACK: Hello. I'm Maia with the American Beverage Association, and I'm representing the nonalcoholic beverage industry. So, essentially we support the comments that Dr. Kavanaugh made this morning in terms of the notion of incremental reductions of some of these nutrients to limits, and she pointed to sodium as an example. We would agree that that should extend to sugars as well, relative -- and this would apply to a number of the proposals that are outlined in this document, as well as the number of the questions outlined, I believe. So, we would support this concept of incremental reductions in sugar in juice standards, for example. And that would help move the needle on national sugar reduction initiatives and goals. Thank you.

DR. BRICZINSKI: So, I'm going to probe a little bit more, if we can give her the microphone back. So, on that, so let's talk a little bit about -- so, what standards, specifically, do you think we would need to look at to address your point?

DR. JACK: So, right now there might be standards -- it's the entire regulatory framework that's presented, so the standards of identity and its linkages to nutrient content claims, and to be able to claim free or sugar reduced, you're required 25% reductions, for example. So, what we're suggesting is why make it so that you have 25% reductions? The regulatory framework collectively should enable industry to innovate and put into the market products that allow for 5% or 10% or 20% reductions. So, that's essentially what we're saying. And do you have --

DR. BRICZINSKI: No, no. So, I mean, I think

we're -- you're okay. We're jumping ahead a little bit in some of our questions. I guess I'm trying to get at more specifically, is there specific products that you have in mind where we could then make that linkage, or you're just talking, you're -- across-the-board?

DR. JACK: That one is across-the-board, but the regulations, also from a minimum Brix requirements, has minimums set, and that could --

DR. BRICZINSKI: For juices?

DR. JACK: For juices. I'm only talking about juices here.

DR. BRICZINSKI: Okay.

DR. JACK: And that could also -- or FDA could also entertain reducing the minimum Brix requirements as well, because right now -- to align with Codex standards. And Codex recognizes, for example, 10-degree Brix for orange juice, in particular.

DR. CHOINIERE: Are there other standards that -- well, I'll let -- before I throw in another question, I saw this hand first.

MS. CULP: Julie Culp from General Mills, and I do have a little more general comment, so I don't know if I'm derailing us. But in terms of overall barriers, right? So, General Mills sells a lot of -- manufacturers a lot of mixed foods, right? So, a lot of times ingredients that have standards of identity are used in those mixed foods. So, in terms of looking at reducing overall nutrient contributions from some of the nutrients of concern, when we're looking at standards of identities within a mixed food and you have a meaningful contribution of perhaps a negative nutrient, that really does limit our ability to reduce the overall contributions in that food where that's a major component of that overall food. So, just, again, general comment around some of the limitations to enable more nutritious foods.

DR. CHOINIERE: Can you provide an example to illustrate what you're describing there?

MS. CULP: So, I think cheese would be a good example, where obviously that's a common ingredient within a variety of different foods. So, where you're looking at overall sodium targets, for example, in

reducing that in that food, if cheese is a major contributor and we're not able to reduce further within that ingredient itself, it would impact the overall ability.

MR. ZELLER: Hi. Sam Zeller with Unilever. Kind of just to build on that, I do think there are some other examples where we can think of -- where we're limiting in terms of producing products with higher nutritional value. And I guess I'll build off the salt substitutes, right? The example this morning was let's focus in on cheese and alternates to sodium chloride, but I think we need to think broader, right, than across categories. And I'll give you the specific example within the dressings category, where sodium chloride is the only allowed ingredient to be used to stabilize, to preserve certain mayonnaise, right?

In addition to looking at alternates to sodium chloride, I think we have to factor in the broader picture in terms of how does everything come together, right? We're talking about a horizontal approach to standards of identity, but here, on the other hand, we've got the sodium targets that we're soon going to see be released, and we've looked at the drafts that have come out, right? And we've got some concerns regarding preservatives, and if we don't have any alternates to preservatives, our only choice is to lower sodium chloride, we've got potential micro issues. So, we've got salt substitutes to look at, we've got alternates, and then we've got the consumer-friendly language, right? And potassium chloride salt really isn't very consumer-friendly, right?

So, it would go back to, again, thinking of the broader picture is just potassium salt an alternative name that we can use as a salt substitute that can be used in foods that have limited standards of identity? And kind of going back to my original point -- let's think broader across categories than just, right, focus in on a horizontal approach for cheese. Now, granted, this could be a lot more difficult, and cheese is a good example to narrow it down, but I'll go back with sugar substitutes, with salt substitutes, I think that can be extended beyond many more categories than just a few.

MR. WILDGEN: Hi. I'm Gabriel Wildgen, a student researcher at Harvard Law School, and we've been looking into various issues around food innovation and standards of identity. A couple of areas where we've identified issues with nutritional concerns if there's too much rigidity in standards of identity. One is the permitting ingredient substitution. One example is mayonnaise. Probably a lot of us have heard of the issue with, you know, Hampton Creek now called Just, wanting to make a mayonnaise that did not include eggs for consumers that are already watching their cholesterol. Having a cholesterol-free mayonnaise that uses pea protein instead of eggs, it would be a healthier substitute, but they're not allowed to call themselves mayonnaise, and there are many other products that are doing similar substitutions.

The other one would be to permit changes to meet consumer dietary needs. This is something we're already seeing the FDA doing. We're seeing the FDA allow standardized product names to be used as long as there's a qualifier, such as rice noodles. You know, noodles technically are always supposed to be made of wheat, according to the standard of identity, but for people who are gluten intolerant, rice noodles is clearly much healthier. And obviously we're seeing this with dairy, with almond milk, soymilk, oat milk, etc., as a big issue right now.

So, we think FDA should continue to be flexible as long as these easy to understand qualifying terms are used. But we do also think that, as I will comment further during the public comment period, that the FDA should be clarifying that allowance, making clear that that is the policy. Because without that clarification, there may be a hindrance to many other food innovators and they'd be holding back worried that they'll eventually get sued or have to change their labeling through a costly process if indeed the FDA starts enforcing standards of identity more rigidly. Thank you.

DR. CALVO: I just wanted to comment on the question that you asked is what can we do to current food categories to improve the nutrition. And one of the recommendations that I would make based on the data that we've done is to address the issue of vitamin D

insufficiency and deficiency in our population and worldwide. And right now we don't have mandatory fortification as other countries do with the exception of infant formula, evaporated milk labeled A and D. And I would like to recommend that we adapt the new lawful addition of vitamin D that came out in 2016 with the nutrition facts label changes to be mandatory in those products that were listed, which are animal milks, and yogurts already have them, and now higher addition in the plant-based milk alternatives and their yogurts. Now, I think that this would enable specific components of our population that are really under-studied to achieve appropriate intakes of vitamin D. And I can show you some recent evidence from our research to show that that would work.

DR. BRICZINSKI: Okay. So, I think we're moving out of standards into talking about proposed changes, so that's a good transition for us into question No. 2. 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, and we've already got a jumpstart on that. Please share your ideas for specific horizontal changes that would help FDA to achieve its nutrition-related goals.

So, what we're going to do is we're going to go through four different questions. I think we'll start with the first one. There is probably going to be some overlap going back and forth, but let's go ahead and jump into that first one.

So, what specific change or changes could FDA make to existing standard of identity regulations to improve the healthfulness or nutrition of standardized foods? So, now we are talking about standards that currently exist and what changes you might make. So, that would be -- that's a good proposed one. What else --

DR. CHOINIERE: Well, we already heard about sugar.

DR. BRICZINSKI: Sugar.

DR. CHOINIERE: We heard about sodium across all the categories. Are there other types of changes

similar to those or maybe not similar to those?

DR. BRICZINSKI: And maybe I'll go ahead -- I'm just going to merge the first two together, because I think this might be -- it might be good to put these together. So, as we're talking about a specific change that you could make to a very specific standard, an existing standard, which standardized foods or food categories would be impacted by that change? So, what we're trying to get at here is, you know, you can come in with an idea about a change that you want to make to an existing standard, but we want to really do with this group is talk about what are the other implications? So, what other food categories might be impacted that aren't necessarily part of that initial proposal? And that's what we want to try to think about, so if you propose a change over here, how is it going to affect your product over here, even though that wasn't your original intention, okay? So, maybe we can start to talk about that, some of your proposals and how it will affect the food industry as a whole.

DR. CHOINIERE: So, maybe I can ask Maia, given the proposal that you had with the sugar and juices, is there something about that that could potentially impact either positively or negatively another product standard? So, and I missed your name? Sam.

DR. JACK: So, we're in the process of considering those types of implications and we'll be sure to provide more detailed comments by November. But generally speaking, I think some of the questions that are floating around is relative to some of these standardized juices and how that may or may not have any implications associated with blended juices. So, it's not clear what the transition looks like and whether there are any implications there. But those are the types of questions that we're considering.

DR. CHOINIERE: I know Sam was advocating for an approach where we would be considering, if I understood Sam correctly, that whatever standard we're looking at that it is across perhaps all of the standards that we have, not just within a subset of those standards.

MS. DOCKTER: I'm Berit Dockter with the

International Food Additives Council. I think to answer your question about food categories, we're looking at the category baked goods and dairy as it pertains to swapping out, I guess, with lower sodium is the main topic. But looking at using potassium phosphate dibasic or DKP in replace of disodium phosphate, or DSP. These two ingredients, right now DSP seems to be more commonly used in baked goods and dairy foods as an emulsifier, a leavening agent, control acidity. So, I think -- and there's also calcium phosphates, there's some, obviously, potassium chloride. We've talked about some other sodium substitutes, but I think the trick is that if industry as a whole decided that they're going to swap one ingredient for another, but another product uses something else, what implication does it have on labeling or the leavening of a product, the pH of the product? So, then bread is maybe not going to be the same bread as another company. So, I think that that's where the real scientific ingredient standards are important, to make sure that if we are making these broad, sweeping changes, or what would be acceptable in the foods that we understand the broad labeling impact, and that kind of thing. But ultimately, you know, we've been looking at more of these ingredient substitutions from a formulation perspective of how it could help with the sodium reduction.

DR. CHOINIERE: Did you have more to add, Sam?

MR. ZELLER: Sam from Unilever again. I guess I was just going to maybe propose preservatives as another category that we might want to think of. And, again, I think the bigger picture with salt reduction initiatives and if sodium chloride is functioning primarily as a preservative. And we might look to lower -- some categories are limited by the inability to utilize preservatives, or may have a very prescriptive list of preservatives that could be used. A little bit of the trade-off, right, is the same clean label issue that I raised before, right? Preservatives typically have a pretty chemical-sounding name, but nevertheless I think it's from a horizontal approach we could maybe consider preservatives in addition to salt alternatives, sugar alternatives, and maybe these types of

preservatives in standards that are currently either limiting or do not allow preservatives whatsoever.

DR. BRICZINSKI: So, I'm just going to help our note-taker catch up here just a little bit. So, let's capture something about --

DR. CHOINIERE: We talked about preservatives and we --

DR. BRICZINSKI: Multiple effects? Multiple effects of ingredients? So, just multiple effects of ingredients, and I think salt is a great example where that has multiple effects, technical effects in a food that we would need to consider. Again, if we're going across categories, there would be a lot of different functions we would have to consider as we go across all those categories if we were to make such a change.

MR. ST. AMANT: Brent St. Amant from Prime Label Consultants, and I'd like to propose the creation of new nutrient content claims. So, the FDA has its existing regulations for foods named by the use of a nutrient content claim in a standardized term. That already applies to essentially all standards. So, if you created, say, a low carb claim or reduced added sugar claim, these could be helpful for people who have restricted diets, say, diabetics, and this would apply horizontally to all standardized food products.

DR. CALVO: One other consideration that I think has to be made, in addition to what are the changes in technical properties when you swap something out, is you have to also look at the nutritional impact on diseases that were not as popular that we're looking at. For example, potassium and phosphorus, those impact people with renal disease, and diet is the only way that they have of maintaining maintenance and delaying progression. So, I think these need to be considered, too, in particular, if the content is going to go up with respect to phosphorus, because this can be very damaging.

DR. CHOINIERE: So, we're talking about not only do we have to consider when we make these across-the-board changes allowing for its substitution for technical purposes, that there may be some unintended health consequences for certain populations. Is that what --

MR. ONLEY: Hi. Mark Onley with The Good Food Institute. Continuing on that idea of sections of the population with specific dietary concerns, you think about the 30 to 50 million Americans with lactose intolerance, that these are folks that aren't able to consume dairy and are interested in that major allergen not being in their food products. So, allowing for these broad kind of qualifiers saying dairy-free or based on plants, or something like that, I think would allow for the use of standardized terms that people understand the function of the food that they want to consume. You know, how they're going to use it on the plate, but also understand the implications for their health, kind of in the way that the gentleman from Harvard proposed.

DR. CHOINIERE: Any more on that question? Other thoughts on that question, or any responses to some of the things that you've already heard?

DR. BRICZINSKI: I was going to say, is there anything that you've heard that you think might be a concern in your product? I think that's part of the dialogue that we're hoping to get here today, is how this all interacts.

MR. WILDGEN: Again, I'll address this more in my public comments, but I just want to make you all aware who aren't aware that there very likely would be a First Amendment issue if you were to start enforcing standard identity on terms like soymilk, almond milk, unfortunately, herbal tea. So, that's something to be aware of. If you don't have a substantial government interest in making a change, then it would be an unconstitutional restriction on a commercial speech to do so.

DR. CHOINIERE: Any other thoughts before we move into the next -- are we ready to move into the next question? Anything you heard that you want to follow up on?

DR. BRICZINSKI: I think we're good.

DR. CHOINIERE: All right.

DR. BRICZINSKI: Okay. So, now I'm going to look at the third and fourth questions for No. 2. So, I think we've been getting at some of this, but how could the change improve the nutrition or healthfulness of the

food? And then I think we spent some time there, but let's spend a little more time on that fourth question, which is what are appropriate limits to the flexibility to ensure standardized foods continue to meet consumer expectations? So, are we going to make it a free-for-all? What do you think? What would be reasonable? Do we need to put some guardrails in place? How would you suggest we approach that?

MR. WILDGEN: Sorry, I don't mean to dominate the mic, but I think reasonable is the word of the day. Courts have already been ruling on these kind of questions, especially when it comes to dairy again. And as long as there is no, what the courts would consider a reasonable consumer would be confused, then there is no consumer confusion as far as what is legally appropriate. I don't know if that is addressing your question.

DR. BRICZINSKI: No, so I think you're getting more into naming, which is different from standards of identity.

MR. WILDGEN: I see, yeah.

DR. BRICZINSKI: So, like the plant-based RFI that was mentioned earlier, right? So, that's really a naming issue. So, while it's part of our nutrition innovation strategy, because it's providing consumers with information about those products, that's really a naming issue. What we're trying to get at is the actual standard itself for the standardized product. So, I just want to make sure that we understand that there are two different issues and we're --

MR. WILDGEN: So, I misunderstood the question, okay, sorry.

DR. BRICZINSKI: Yep.

DR. CHOINIERE: So, we already heard one guardrail, at least I heard one guardrail, was that if we maybe loosen up our -- the prescriptiveness on the specific preservatives that we're using, that maybe we need guardrails around certain types of preservatives that may adversely impact the health of certain subpopulations.

DR. BRICZINSKI: The overall diet.

DR. CHOINIERE: Or the overall diet.

DR. JACK: So, I think my comment is going to

align perhaps with this gentleman's here in that I think that there is two conversations here, and I think this -- I'm not sure if I'm understanding correctly the question, but I think there is a tie-in to the consumer understanding as well. So, relative to limits that you're requesting for one piece of that would be consumer disclosures. And so what would that look like with the various proposals that we're putting forward? So, it's a question, and we're putting some thought into that.

DR. BRICZINSKI: Okay. So, we were hoping to get some good discussion. If you look right above the discussion questions, there's six proposals that industry submitted in various venues. And if we could maybe, like -- so, look at some of those and maybe consider. So, I mean, again, someone has proposed this; how would it impact your products in either a positive way or a negative way?

DR. CHOINIERE: And by virtue of us listing them here, it does not constitute an endorsement --

DR. BRICZINSKI: Yeah.

DR. CHOINIERE: -- or any -- we're just providing these as -- these are proposals that we've heard and that we want to share with all of you to get some input on whether or not any of these proposals might be broadened to be more -- many of them are very specific to certain categories or standards, so broadened to be more horizontal in nature, or if they may have an adverse impact on a different food standard or food category.

MR. DETLEFSEN: Clay Detlefsen with National Milk. I'll speak to proposal 5, where the parenthetical says eliminating milk fat requirements in standardized products. I don't think that's necessary. First of all, I'm not sure why milk fat is actually being vilified here. I think the science is changing and people's perceptions are definitely changing. I mean, butter, for example, is selling out like crazy these days, whereas, margarine is in the toilet. But, any rate, you can already do a lot of things without having to tinker with this milk fat requirement. And if you want to make imitation cheese, you can go ahead and do that. If you want to make a frozen dairy desert, like Breyers, go look in the freezer case in your grocery store. You'll see a

ton of would-be ice cream products that don't meet the standard of identity but they're there and being sold. So, if you wanted to substitute vegetable fat, you had some reason to do so, for milk fat in a dairy product or a frozen dairy dessert, you'd have a product called mellorine; there's a standard for that. So, there are options available right now. So, you know, I don't think it's -- I don't think pursuing milk fat would really benefit anybody.

DR. CHOINIERE: Any other reactions to some of the proposals that are listed here, or to the last comment?

DR. BRICZINSKI: Are there any others on that list of six that you like? Any on that list that you don't like? Any concerns? Again, any guardrails that you would put up where you might say, well, I agree with proposal No. 2, but I would suggest it be limited in a certain way. And this is where we're really trying to get some good dialogue.

MS. CHEN: This is Liwen Chen from Fonaly Consulting. I would like to make some comment to proposal 2, permit enrichment to replace ingredient loss during the processing. When we work on this, we really need to consider the upper level of this ingredient to human body. And also, during the processing, actually, how many -- how much amount of this ingredient lost? And usually when we do the nutrition fortification, we usually over-enrich it, so the upper level of the enrichment should be very carefully addressed.

DR. BRICZINSKI: So, that might be one guardrail that we should note.

DR. CHOINIERE: All right. So, are there any proposals that any of you have that have not already been articulated either in this list or in our discussion today? We had some new ones that are not on this list that we heard today related to sugar and preservatives, or maybe they are on this list. Actually, proposal 5 is the sugar. We heard about nutrient content claims. We haven't heard a lot about fortification -- well, we heard fortification in terms of particular nutrients, but we also have beneficial ingredients, such as adding whole grains. Are there standards in place that would restrict

that? I'm not a standards expert here.

MR. ABEGAZ: Okay. I'm Eyassu Abegaz with Ajinomoto North America. So, in addition to what was said about preservatives and sweeteners, another we may consider is perhaps like some ingredient that may have technological functions as far as texture. For example, in some dairy products, the enzyme of interest mentioned is rennet, but there are other kind of enzymes that has been since developed to have similar functions, microbial fermentation enzymes. So, for example, transglutaminase, so sometime being very specific to rennet, so it doesn't allow for other ingredients to be used in those categories.

DR. CHOINIERE: All right. Any other examples like that? That's an enzyme in dairy products.

DR. BRICZINSKI: So, I'm going to ask a question for the group. I thought there would be more discussion. All right. Take a look at proposal 3 for me. So, it says permit fortification to add beneficial ingredients, and I think conceptually we all have our own ideas. You know, everyone probably has their own idea of what that means. So, let me ask you, what is a beneficial ingredient?

MS. DOCKTER: I'm Berit Dockter. I am speaking on behalf of myself as a registered dietitian. I went to college in Minnesota, and when you think about echoing the comment about vitamin D, so my comment really is related to vitamin D. You know, as we saw this push for more low fat dairy, the cheese production had ramped up, what was that, in the 1980s, and so at least in the Midwest you do have quite a lot of folks who use yogurt or cheese as more of their primary calcium source, for example. But these are not widely fortified at the same level with vitamin D as you would have for fortified milk, for example. So, that was always something that my professor observed that I think people that are in the latitude above Denver could benefit from a little bit more vitamin D. You know, we know that it's going to be now on the label a little bit more, so I think that that's something to consider. So, I would add vitamin D to the list.

DR. BRICZINSKI: So, would you -- so, I'm just

asking. So, would you go through, do you envision, if we talk about beneficial ingredients, like having a list of beneficial ingredients, or do you anticipate tying a nutrient to a health benefit? Like, how would you suggest we go about doing that?

MS. DOCKTER: Well, if vitamin D is going to be called out now on the new nutrition facts label, I think it will be more and more obvious on some of those common dairy foods or dairy substitute foods that normally folks go to get their calcium source. But we know the value of having vitamin D with the calcium, and that's up for the manufacturers to decide how that looks, what level and that kind of thing. But my personal opinion is that people are using not just milk to receive the calcium, vitamin D sort of category, but it's not at the same amount that you would value from the vitamin D that would be in a fortified milk, per se. And, of course, you know, hopefully the amount of maybe cheese, for example, the quantity is limited. But, anyway, I think that's something for people to figure out.

So, to answer your question about a list, I mean, it's kind of already going to be on the list, if you count the label. I'm just brainstorming right now, so I just want to throw it out there.

DR. BRICZINSKI: This is good. This is good. No, what I'm trying to get at is who makes that list? What criteria? Is it based on -- oh, I'm sorry, go ahead Clay.

MR. DETLEFSEN: Would it be more obvious when the FDA comes out with its definition of healthy? I mean, you guys got to put that out there, then we'll tell you what's beneficial.

DR. BRICZINSKI: We've got a lot on our to-do list.

DR. CALVO: Maybe I can help with that question. After 30 years at the FDA, anything that we ever reviewed had to be consistent with the dietary guidelines for Americans. And so, every five years this is renewed and looked at again, and since 2005, vitamin D has been on the list of limited essential nutrients. And every year that can change a little bit, but it stayed steady for vitamin D. So, I think that you can use that

authoritative body to help dictate what is a beneficial nutrient. And, also, what's limited in our food supply, because that's what's critical, because vitamin D is clearly limited in our food supply.

DR. BRICZINSKI: Okay, so this is good. Now, I'm going, okay. I feel like we're warmed up. So, okay, so let's talk about nutrients, a public health concern, right? Because that's what those are, and that list changes every time the dietary guidelines is revised. How are we as FDA going to respond to that when we're talking about standards and trying to make them more evergreen? So, how can we allow for that type of flexibility knowing that there's going to be advances? And maybe I'm jumping ahead, I think, in one of our questions. But how do we allow for that advancement in nutrition science and our understanding of nutrition without having to say oh, my gosh, there's now another list of nutrients of public health concerns. Some fell off, some came back on. Now we've got to redo our standards again. I mean, do you guys have any sense or input into how we might be able to do that? I know some of you are laughing at me, but any thoughts on that? That would be great.

DR. CHOINIERE: Yes, for any of you who have been involved with rulemaking, you know that it's a long and arduous process, and so that's why we're here today talking about standards of identity that can be very rigid once you put a rule in place. And so how do we get horizontal standards in place that could allow us for greater flexibility for the advances that we are seeing in science and technology in the food area, food sector?

DR. BRICZINSKI: Sam's laughing, so I don't know if he --

MR. ZELLER: Sam from Unilever again. I don't have any answer to your question, but I just point out, right? I certainly acknowledge dietary guidelines in terms of shortfall of nutrient concerns. Many of us use that as a real guidepost. But just looking at vitamin D, we're very, very limited in the existing food additive regulations in terms of what we can add vitamin D to. So, we can call it out, right? We can't add it to anything -- very few things. So, I don't have the magic

bullet, but if there was a way to tie it into that ever-evolving dietary guidelines in terms of -- I don't know what the regulatory mechanism is, but that would certainly be a guidepost for us.

MR. WILDGEN: I guess I just want to mostly respond to your previous question about who should be making the list of beneficial ingredients, and I'll answer an inverse of who should definitely not be. And I would say definitely -- I'm sorry to some people in the room, but not people who are representing industry interests, who have invested economic interest in determining what is and is not beneficial to consumers from a health perspective. I think there's a lot of room for input from industry on innovation questions, on marketing questions, but when it comes to actually determining what is healthy, I think, for instance, the government of Canada has done a great job of this recently. They did not allow any industry input when it came to creating their new food guide for Canada. And as a result, dairy is no longer even a food category in Canada, and there is no minimum intake of dairy now required in Canada. So, I think that was clearly a shift away from the previous food guide, which had tremendous influence from the dairy industry, and so I think that FDA would do well to follow that lead.

DR. CHOINIERE: I'm not sure we can legally do that. Is there any other thoughts? Because we're kind of -- now that you also mentioned an international body, perhaps we can also cover the third question, if there are -- if you are aware of any existing food standards that have been established by either voluntary standard-setting bodies or regular counterparts, such as Canada or other countries, that could be a model for FDA to use in order to achieve our nutrition goals? And we have been very focused on the standards that are already in existence in our FDA rules, but perhaps there are other models around the world that we could -- we weren't aware of, right? But we wanted to throw that question out there.

MS. WU: Sorry to throw a question off a question. I'm wondering how country FDA actively monitoring other countries food regulations, their

updates, in order to obtain the information of the changes of other, like EU or China, or any other country who is currently actively updating their regulations, or reform their regulations on food?

DR. CHOINIERE: We monitor that quite closely. I mean, we are active in numerous international organizations such as Codex and World Health Organization, as well as we have, also, some more informal arrangements with certain countries as well, where we share information.

MR. WILDGEN: I just wanted to clarify my previous comment, because I think it would be illegal, as you say, not to allow public input from industry on these questions. But I was just advised no private lobbying, that any communications from industry to the FDA on these questions should be made public, and that's what Canada did.

DR. JACK: Hi, Maia, American Beverage Association. So, we would support alignment with Codex standards. However, the caveat is that in some cases these standards haven't been revisited for more than a decade or two. So, Codex also is in need in modernizing their standards. So, that's just a call out.

DR. CHOINIERE: Yes. It's hard enough to change rules in one country, but to try and get multiple countries aligned is even more difficult. Do we have any thoughts on anything that we spoke about today, or anything that we didn't touch on today that we want to make sure gets shared before we -- how are we doing on time?

DR. BRICZINSKI: We're very good on time.

DR. CHOINIERE: Good time?

DR. BRICZINSKI: Yep.

DR. CHOINIERE: All right. Any other questions you have, Beth?

DR. BRICZINSKI: I mean, I can ask you guys questions all day. Does anyone want to share something? I can keep going. Go ahead.

MR. ZELLER: Just looking at question No. 4, I don't know if this belongs in this session or innovation, but I think the alternate technologies, new food technologies is still a way to think about improving

nutritional profiles, and I'll get back to the prescriptive nature of certain food standards that don't allow for those alternate technologies. So, again, I don't know if this is within question 4 or the next session.

DR. BRICZINSKI: I think it is the same question about --

MR. ZELLER: Then I think we'd throw this back up, then, and I think this was raised back in 2006, with the GMA citizens petition as well.

DR. CHOINIERE: Any other thoughts on the innovation issue related to nutrition?

DR. CALVO: I think one way that would be very innovative is across all of the categories where lawful addition of vitamin D is allowed, that it goes from voluntary or optional to mandatory. Now, other countries have done this, and Finland, for example, and it's working extremely successfully there. These are high latitude. Canada does the same thing. Canada has mandatory fortification in milk. We all have different levels, but there's a variety of foods that America fortifies with vitamin D, and if this was made mandatory, I think we'd have an enormous improvement in our intake without reaching toxicity.

MS. CHEN: This is Liwen Chen from Fonaly Consulting. Yeah, about the vitamin D fortification, I want to share my thought. Vitamin D is a fat-soluble vitamin, so comparing to water-soluble vitamin, like folic acid, the tolerance for vitamin D would be mostly than water-soluble vitamins. So, for some kind of food I think it's good to have some mandatory fortification in order to increase public health, especially for those groups with vitamin D deficiency vulnerability. But it really depends on the consumption of the food we eat. If some kind of people center, consumer group, consume a lot of vitamin D fortification foods, maybe they could consume too much vitamin D.

So, I think it really depends on the monitor of the post fortification and see if it really were to all the food or just some kind of food, and also watching some of the vulnerable consumer center, consumer group. So, how do you think?

DR. CALVO: This comes under the responsibility of what is done in CFSAN, and this is highly vetted. We use the NHANES data for consumption, which is nationally representative, and we go -- when a petition comes in, for example, orange juice, when it came in, to look at what populations this will affect given current and then putting it in every product with that -- in that food category, to see if it reaches the UL. And so I think that that's not an issue with vitamin D.

In addition, in the history of vitamin D fortification, there has only been one report of toxicity, and that was related to an accidental poisoning in a Boston dairy, where the individual did not measure it and just poured it in, and a lot of people suffered from that. But your bigger danger is in the use of dietary supplements, which FDA doesn't regulate.

DR. CHOINIERE: We have limited regulatory authority, let's put it that way.

MR. DETLEFSEN: National supports vitamin D fortification of dairy products, milk in particular. But what do we do when consumers don't want fortification? There was a case down in Florida where a dairy company wanted to make skim milk without added vitamins and that ultimately went through the courts and was quite a mess. And right now, I believe FDA is currently in litigation with South Mountain Creamery, which basically, again, doesn't want to put vitamins in milk. I mean, sometimes we have to give consumers what they want, but what I'm hearing from the room is this very strong desire to fortify. But how do you deal with that when there's definitely a population out there that doesn't want fortification?

DR. CHOINIERE: That's a good comment, and I hope you go to the consumer expectation session.

MS. WEBSTER: Hi. Allie Webster with the International Food Information Council. I have a question related to fortification and maybe using vitamin D as a specific example. When you mentioned -- the woman in the front of the room mentioned that Finland has mandatory vitamin D fortification in certain products, and that it has been a success, could you tell us about what exactly the benchmark for success is? And I think

this gets at maybe tying the fortification or benefits into a health outcome. So, we can fortify things to the degree possible, but I wonder how we measure the success of that fortification, if it's actually making an impact when it comes to our health?

DR. CHOINIERE: So, I think what I'm hearing is, so with folic acid we could measure the success with the neural tube defects, how would we do this with vitamin D?

DR. CALVO: Well, there's a lot of ongoing studies right now, but in Finland what they use is what we use here in the United States, and that's -- we look at the intermediary metabolite of vitamin D. Vitamin D is actually a hormone, but we just can't make enough of it in our skin. And so the intermediary metabolite is 1,25-dihydroxyvitamin D, and so that's used right now as the standard for when we say there's insufficiency in the United States, or this individual is deficient. If you go and have your D analysis done, Quest, or whatever laboratory is doing it, will give you the readout of where you fall on that. So, that's what's used in Finland right now. But in addition, they're looking at chronic diseases that take time, and so there's a lot of epi work that's very -- it's associative, it's not causal, to show that indeed when you have higher levels, things change. And you also prevent other disorders, like hyperparathyroidism, which occurs when you have a low vitamin D level. Does that answer your question?

SPEAKER: [Microphone inaccessible.]

DR. CALVO: Yes, yes. Yeah, in particular --

DR. BRICZINSKI: Could you repeat her question so the microphone can capture it?

DR. CHOINIERE: So, you were asking if the data that she was referring to is out there related to this impact of vitamin D.

DR. CALVO: Yeah, one just came out. The first author is Suvi Itkonen, and it's about how they look at more than one fortified food in Finland and how it's changed. Finland has one of the highest rates of diabetes in the world, and it's very high latitude in the Land of the Midnight Sun, so they do not really get a lot of sunshine up there to produce D, so it's a major issue

in those countries.

DR. CHOINIERE: Okay. We have a few more minutes before we're going to wrap up for a summary.

MS. CHEN: Yeah, just a brief comment about mandatory fortification proposal of vitamin D. For some kind of product, like skim milk product, technically it could be very difficult for vitamin D fortification, because no --

DR. CALVO: Vitamin D is well absorbed from low fat products. So, yes, fat facilitates D absorption from the gut, but it's not necessary. Michael Holick's work.

MS. CHEN: My point is how to fortify. How do add the D, vitamin D, into the milk when there's skim milk, when there's no fat, so there is no vehicle to put the D into.

DR. BRICZINSKI: So, maybe to capture this generally, I think what we need to do is when we're talking about fortification, consider the delivery, the vehicle, bioavailability, how it's absorbed in the body. So, maybe not vitamin D, specifically, but just in general look at that fortification and how that's done.

DR. CHOINIERE: All right. Any last thoughts on anything we talked about today?

MS. CULP: So, Julie Culp, General Mills. I think obviously it's great to hear some of the specific examples, and, of course, I can admit to having gone through this full exercise myself. But my gut is still that a lot of these would ladder up to many of the categories that were proposed in the 2006 industry petition, and so I would just reiterate, I feel like that is definitely a more efficient approach and may ultimately address a lot of individual ideas that have been raised.

DR. CHOINIERE: That sounded like a great final comment, actually. So, I think we can springboard off from that and try to kind of echo some of the things that we heard today.

We certainly heard a lot about specific standards that folks have a vested interest in and want to see changes. And in a little bit about how a change to some of those standards could be perhaps carried across all of the standards, whether it be fortification

with certain ingredients or the allowing substitution for either something that's used to impart flavor or something that may have some technical effects, either emulsifiers or preservatives. What else did you hear today, Beth?

DR. BRICZINSKI: So, let me go look. So, I'd like to comment talking about how we need to consider the interaction between standards of identity, other nutrition policies and consumer demand, and I think that's what we're going to try to get here today. But I think it is really important that we capture that, consumer demand in terms of how natural or clean label your product is, and the implications that that might have on something that we're trying to do.

DR. CHOINIERE: And I know that we have some folks that will be taking all of these notes and trying to pull them into some themes by the end of today, so we'll be able to capture those themes and share them with you at the end of the day. And we'll also take some time over the next few weeks to create some sort of a summary -- that's correct, right? And that summary will be made available on our Web Meeting page. But if there is anything that comes to you after today's meeting, we encourage you to submit a comment to the docket. And even if you haven't already submitted these ideas to the docket that you go ahead and submit these to the docket as well. And so --

DR. BRICZINSKI: And so on that, I think from the staff perspective, the more specific you can be in your comments the more helpful that will be to us in terms of understanding the changes that you might prefer or not prefer, how to put those guardrails in place. You have a handout in your packets on how to submit to the docket. The only other note that I'm going to make is next steps. So, after this we're going to break for lunch, come back at 1:00 for the second round of breakout sessions. The Nutrition breakout session, if you want to do this all again, we're going to be in the Plaza Ballroom, where we were this morning. If you want to come back to this room, in this room will be the Innovation breakout session. And then if you want to do Consumer Expectations, that will be in the Regency

Ballroom.

DR. CHOINIERE: It's just down the hall here.

DR. BRICZINSKI: Yep.

DR. CHOINIERE: All right. Well --

DR. BRICZINSKI: I was going to say, any other closing comments or otherwise I want to say thank you very much for your participation and for being here today. All of your input is very, very valuable, so thank you so much.

DR. CHOINIERE: Thank you.

(Whereupon, at 11:38 a.m., the breakout session was concluded.)

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