However, I do know that consumers know there is, for example, milk in this product, I don't care how long you tell them it is they are never going to eat it, if it is labeled that way.

I don't really see a harm in picking the lowest maybe for now. For example, right now the thresholds for peanut are being worked on, so I don't really see the harm in picking the lowest and using that as a guidelines just to start with until we have better methods.

If you tell a consumer, I mean, "Yes, it has caseine" or don't label it at a higher label, it doesn't matter because they are still not going to eat a product that has that. They would much rather know it is at the lowest possible level and avoid it than to not label it because it is going to limit their choices. They wouldn't have eaten it in the first place anyway. They just want to know that it is in there, if that makes any sense.

MS. MUNOZ-FURLONG: Right.

DR. MALEKI: It would be preferable to just have the lowest possible limit you have and

then say --

DR. BRITTAIN: Do you mean the limit of detection? Is that what you mean?

DR. MALEKI: Like, right now we know peanuts -- Soheila Maleki -- and, again, whether you want to consider the most severe food or the more prevalent food, that is a question that comes up.

In this case, threshold levels for one of the most severe food allergic reactions, which is peanuts, is being determined. We are pretty close to that. Could that actually be used for other foods?

I know it seems like a cookie-cutter type of choice, but, on the other hand, I wonder if the food-allergic consumer wouldn't much rather have that than wait around for another 8 to 10 years until they figure out what the thresholds for the other foods are. That is just a comment.

CHAIRMAN DURST: Jean?

MS. HALLORAN: Actually, this is a question for FDA, but I'm not sure FDA has the

option to wait around for 8 or 10 years. I think it has to put out rules in the interim.

Their final question here is if you don't use peanut as your threshold for other categories like soy where you don't have much data, is there a more appropriate method to use? That is their final question to us. I am having a hard time thinking of a better alternative, so I agree with Dr. Maleki. DR. MALEKI: Soheila Maleki. I agree. Again, we have pretty much, just based on discussion that has come out said you can't really set a method because you don't have the data. You can't do modeling because you don't really have the data. Right now, Dr. Hefle and Taylor are working on organizing a group or have already started doing the first real valid threshold dose studies that are happening. This is data that is going to be available, hopefully, soon.

At least it is something to go on versus waiting around like she said, because there is no funding, it takes a year, it takes $200,000 or so to do it. Do we really want to wait for that to

happen?

CHAIRMAN DURST: Dick Durst. That is certainly erring on the side of security and safety. The other side of the coin, though, is now you are going to be limiting people's abilities to get foods that would be perfectly safe for them, but it has now fallen into this threshold level that, you know, says, "Oh, no, if there is something in there, don't touch it."

I'm not sure, maybe a person with an allergy would rather not have to try and have access to some of these other foods, if there is even the slightest chance of an allergen being present.

DR. MALEKI: If I can answer that real quick. As of now the detection kits that can detect, for example, a product like this, that says there is soy product in this candy bar or whatever, that kit can detect a very, very low limit. The industry is already labeling that as "may contain." They are already not going to eat that product.

Do you see what I'm saying? As far as the

level of detection of the kit is below what they would touch anyway. I don't know if it would limit their choices. I think they would rather know.

DR. NELSON: This is Mark Nelson. I don't think that is an accurate generalization about the label.

DR. MALEKI: Okay. Go ahead.

DR. NELSON: No, I was just going to say I don't think that is an accurate generalization about the label.

DR. MALEKI: I'm sorry? I don't understand.

DR. NELSON: Just because a kit detects it, depending on the sensitivity of the kit, it may not necessarily be labeled if it is below a certain level.

DR. MALEKI: Soheila Maleki. Can you comment on that a little further? What do you mean by that?

DR. NELSON: I think it refers to the rule of thumb that Steve Taylor was talking about earlier, that a lot of the industry has been using

in the absence of specific regulation.

DR. WASLIEN: Which is what?

DR. NELSON: It depends on the company, what they use. Some of them use 10, some of them use 5.

DR. WASLIEN: Okay.

CHAIRMAN DURST: Okay.

DR. MALEKI: Soheila Maleki. I agree with you, but the level still is pretty low is it is higher than 10 parts per million or 2 parts per million.

DR. NELSON: Yes, it is.

DR. MALEKI: We are not talking -- it is not like the ingredient is there.

DR. NELSON: Right.

DR. MALEKI: All the "may contains" now will be based on new label rules that will say "contains." It is no longer to be "may contain."

DR. NELSON: Exactly, but there is an ingredients label.

CHAIRMAN DURST: Okay.

Jeff?

DR. BARACH: Jeff Barach. I do agree with the Chair and his comment about the fact that if the level is set at the lowest possible level for all allergens that we will see a proliferation of labels that do contain information on allergens, and that will limit the food choices for the allergenic population.

To get to the last part of the question that was brought up earlier, is there a more appropriate method to use? I don't really subscribe to that method, but if we are forced into a box and we have to choose that type of method, I would say that there is a possibility of grouping some of these allergens together. That may be to an advantage.

The levels of, say for instance, soy and wheat are much higher than perhaps for peanut protein, so there may be some opportunity to group, say for instance, nuts, peanuts and soy and wheat together to set levels rather than choose the lowest for everything, which would cause a lot of problems.

CHAIRMAN DURST: Okay.

DR. MALEKI: Just real quick. Soheila Maleki. Again, it is in the absence of data, so you can't group things together when there is no data for the rest of the groups. Of course, that is assuming you want an answer soon.

CHAIRMAN DURST: Okay. I would just like to suggest the Chair has arbitrarily set 6 o'clock as our deadline, so why don't we just quickly discuss, we have 15 minutes left to discuss the last part, which we touched on already, these highly refined oils. Would anyone like to make some comments on the questions in there?

Petr?

DR. BOCEK: Petr Bocek. Well, we know that there are allergens which the epitopes are confirmational. They are epitopes which are linear. Some preliminary data from Hugh Sampson's lab are showing that people who are allergic to the linear epitopes are actually more prone to the more severe reactions.

I don't really know what the construction

entails, but I would be really concerned about the denaturing of the protein and losing some of the epitopes which would be allergenic in the protein in the oils. That may be a reason that just the level of the protein and the allergenicity of the extracted oil may not be very well correlated. I would have a problem with that.

CHAIRMAN DURST: Anyone else on that topic? That was a good point.

DR. WASLIEN: You know, there is also the question of oil level itself influencing the absorption of allergens. If you are using high-extraction oils as a standard, you are sort of giving yourself an added safety factor, not safety but a protective factor for setting limits or too high a limit because of that oil protection or oil interference with absorption. You may be using protection when I shouldn't be using protection, but that factors in there, too.

DR. MALEKI: Soheila Maleki. I would like to refer that to one of the panel members, either Steve or Sue, which have done studies with oil, or do you have anything to say

with that as far as can the oils be used, the protein level in the oil being used, to determine the thresholds?

DR. TAYLOR: (No microphone.) Since I have absolutely zero confidence in the protein levels that have been published in oil, I wouldn't presume to use this approach to write regulatory standards.

(General laughter.)

DR. MALEKI: Steve, I knew I'd get an answer out of you on that one.

DR. TAYLOR: (No microphone.) It's late in the day.

CHAIRMAN DURST: Yes. Dick Durst. As Petr said, I think that would probably give an erroneously high threshold because of the fact that you are looking at total protein, and it may be that a lot of it has been denatured to the point where you still detect it as a protein, but it does not have the allergenic effect any longer. I think that was a good point.

Yes?

DR. KELLY: Ciaran Kelly. Could that problem be overcome or reduced by using an enzyme immunoassay for detection? Have any studies like that been done, or has it always been totally protein?

MS. MUNOZ-FURLONG: (No microphone.) No, no study has been done using ELISA. I don't trust those either for oil substances, using it in not-risk kind of situations. I don't trust the data any more if you have the ELISA test. IgE levels have been used in some cases, too.

DR. KELLY: Are there any circumstances where antigenic activity was identified in these oils.

MS. MUNOZ-FURLONG: Yes.

DR. TAYLOR: (No microphone.) Yes, there are --

MRS. MOORE: Excuse me. If you don't talk into a mike, it might not make it into the transcript, so I'm going to have to ask you to go ahead and repeat, because we've gotten in trouble for that in the past.

(General laughter.)

MRS. MOORE: Just summarize what you just said.

DR. TAYLOR: Traces of IgE-binding proteins, allergens, are present in oils, that is for sure. The problem is there is so little protein there and it is so hard to extract it out of the oil into an aqueous environment so that you can use aqueous testing systems.

The results are probably somewhat below the lower limit of sensitivity of the testing systems that have been used. Frankly, I don't yet trust any of the data that exists on protein levels of oil.

That opinion is the same as the European Food Safety Authority's expert panel in reviewing data on soybean oil and peanut oil. They said they trusted the clinical data that was done, but they didn't trust the protein data. They are making the industry in Europe go back and develop actually a better protein method, which I hope they will be successful.

DR. NELSON: Steve -- this is Mark Nelson -- there is data from a clinical standpoint about soy oil and its reactivity?

DR. TAYLOR: No. We finished the soy oil clinical challenge trial using that famous 29 subjects.

(General laughter.)

DR. TAYLOR: None of them reacted to highly refined soybean oil. We took 30 soybean oils from 30 different facilities around the world, and we tested them for protein.

We made an oil challenge vehicle out of the three oils that tested highest for protein using the method that I don't trust, but it was as good as we could do.

Highly refined peanut oil has been suggested. Jonathan Hourihane did a study with 58 people, there have been at least another 20 or 30 challenges in other trials, and nobody has ever reacted to peanut oil in any of these controlled clinical challenge trials.

Usually, with cumulative doses up to 15 or

16 milliliters of oil, which would be equivalent to about the maximum amount you would likely get in a meal.

I think the oils are safe, but if you ask me how much protein is in them, I've got to dance around that. At the moment, I don't think anybody quite knows. It's not enough to provoke a reaction, but there is some there.

CHAIRMAN DURST: Well, the Chair is feeling generous and tired.

(General laughter.)

CHAIRMAN DURST: Unless Marcia has some final comments--? No?

MRS. MOORE: No.

CHAIRMAN DURST: Well, I would like to thank everybody for participating today. I think we start at 8:30 tomorrow morning. Thanks to all of the speakers for their contributions also.

(Whereupon, at 5:50 p.m., the meeting was adjourned, to reconvene at this same place on Thursday, July 14, 2005, at 8:30 a.m.)

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