PRE-REGULATORY WORKSHOP

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

POTENTIAL NEW REGULATION

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A P P E A R A N C E S

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Dr. Melanie Marty, Acting Deputy Director

Ms. Carol Monahan-Cummings, Chief Counsel

FACILITATOR:

Ms. Jodie Monaghan, UC Davis

ALSO PRESENT:

Mr. Matthew Allen, Western Growers Association

Ms. Cynthia Cory, California Farm Bureau Federation

Mr. Trent Norris, California Chamber of Commerce

Mr. Karl Riedel, Natural Products Association

Mr. Anthony Samson, California Chamber of Commerce

Mr. Eric Somers, Lexington Law Group

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P R O C E E D I N G S

ACTING DIRECTOR ZEISE: Good afternoon. If people would like to take their seats. So I am Lauren Zeise. I'm the Acting Director the Office of Environmental Health Hazard Assessment, or OEHHA.

Is this better, Jodie.

MS. MONAGHAN: Yeah.

ACTING DIRECTOR ZEISE: Okay. Are we ready?

MS. MONAGHAN: Yes.

ACTING DIRECTOR ZEISE: Okay. Great. And I'd like to welcome people here in the audience, and on the web. And again, if you would like to message your colleagues to join on the web, it's at calepa.ca.gov, and they just have to hit the webcast button and identify the webcast.

So this afternoon, we are looking at a pre-regulatory proposal to add a new section into the natural occurring section of the regulations. It deals with naturally occurring chemicals in food. And we're starting our pre-regulatory concept or discussion looking at lead and arsenic in certain foods.

So this is the second of four workshops over the next six days that we'll be having, looking at updating or clarifying our Proposition 65 regulations. So we had one this morning looking at the MADL for lead, and we're

having another two next Monday at our offices in Oakland. Those workshops will not be webcast. We'll be having one in the morning and one in the afternoon, both looking at this issue of averaging, one focusing on the average consumer, the other focusing on average levels or average concentrations in food.

So to start our pre-regulatory discussion of background levels -- and again, this is focused on adding a new section to the naturally occurring part of the regulations. So to start it off, first, Jodie Monaghan who is our facilitator will be giving some notes on process. And then we'll hear about the legal aspects from Carol Monahan-Cummings, and then Melanie Marty -- Dr. Melanie Marty, our Acting Deputy Director for Scientific Affairs, will be giving our pre-regulatory concept.

So Melanie is on my left and Carol is on my right. Jodie is over there in the corner. And if you would like to speak, please make sure you fill out a blue card and give it to either Monet Vela or Esther Barajas-Ochoa, there.

Okay. So let's see. So again we're starting our -- thinking about this regulatory concept focusing on two metals, arsenic and lead. And they are ubiquitous. And one knows that, you know, if you take any food and you have a sensitive enough analytical technique, you're going

to find it. They are naturally occurring. And so what we're looking at are methods to establish naturally occurring levels in food. And our proposal sets out a safe harbor for it.

We are trying to hear from everyone who wishes to speak. This particular workshop we have three hours. Hopefully, we can get -- we will be able to get to everyone. But if we have many, many cards, then we'll subtract off a time, but I think we should be fine.

So this meeting is also being transcribed, and the transcript will be made available to the public as soon as it's available. And we're looking forward to a full range of the concepts around this proposal or this concept, but we realize that oftentimes there are a lot of elements you might want to bring up and have -- might have thought about it in quite considerable depth. So we really are looking forward to hearing from you today, but also to receiving your written comments where you can layout in detail any alternative ways of looking at the issue or providing a lot more detail in terms of what your -- what your issues are with the regulatory concept.

So I think, at this point, I'll turn it over to Jodie Monaghan.

MR. MONAGHAN: Great. Thank you. Is my microphone working?

Yes.

So my name is Jodie Monaghan. I'm with UC Davis Collaboration Center. And I'm very privileged to be your facilitator today. My role is to operate as a third-party neutral. My job is to make sure that you all have an opportunity to ask questions, get them answered, and provide comments.

Lauren went over the agenda already. I want to go over a few housekeeping items. For those of you who need it, the restrooms are out the door to your left a long way down. Be sure and wear your track shoes.

As Lauren mentioned, this is being webcast. And should we have an emergency, you need to exit through the doors, turn to your right, go down the stairs, and then out the front main doors of the building.

We've got just a few ground rules, nothing too arduous. I'm going to ask that you all participate fully. And what I mean by that is if you do want to have side conversations, feel free, just take them outside, please, so you're not distracting the other people who want to listen.

I ask that you respect different points of view. The way I look at it is that you approach this with curiosity. General conversational courtesy. I know this is a very professional crowd, and I don't think I need to

say more about that.

I will ask that you respect time when we do get to the people with public comments. I'm guessing we're going to have more than enough time, but we initially have a max of five minutes. And so I'm going to ask you to respect that five minutes. The more you intrude into -- you know, past five minutes, you're imposing on someone else's time, and I'm sure you wouldn't appreciate that.

Take a minute, please silence all your electronic devices. And then one last thing is I'm going to ask you to hold your questions till the end of the presentation. You'll be able to ask questions as part of the comments. Because this is more informal, you'll be able to engage the panel in some back and forth.

So just a show of hands, how many people are thinking, at this point, they might be speaking?

(Hands raised.)

MR. MONAGHAN: Okay. Looks like we'll have more than enough time. We do ask that you fill out the blue speaker cards and give them to Esther, Monet, Julian, if he's still in the room. Julian or myself.

So any questions before we get started?

Great. Then I'd like to turn it back to Carol.

(Thereupon an overhead presentation was presented as follows.)

CHIEF COUNSEL MONAHAN-CUMMINGS: Thanks, Jodie. Am I on?

Can you guys hear okay?

Okay. There it is.

All right. Good afternoon. Once again just for purposes of this hearing, we're assuming that the folks that are attending, either on the web or in person, are aware of the requirements of Prop 65, and so I'm not going to go through the law itself.

But what we're doing today -- actually, I don't know why we're at this one.

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CHIEF COUNSEL MONAHAN-CUMMINGS: Okay. Anyway, what we want to talk about today is a pre-regulatory proposal. And given that we don't have a hearing that's kind of overlaid like we did this morning with the discussion, we can have a little bit more of an interactive process. But what we would like to do is just go ahead and give our presentations first, and then we can answer your questions afterwards.

So in terms of naturally occurring chemicals in foods, as some of -- early commenters have pointed out, and often, the statute doesn't talk about whether or not a chemical is naturally occurring or not. The statute just requires warnings for exposures to chemicals that are

listed under Prop 65.

But many years ago, the lead agency developed a regulation about naturally occurring chemicals in foods, because as Lauren noted, there are chemicals in virtually every food that are on the Prop 65 list. And so we wanted to address some of those kinds of exposures differently than we would for other kinds of products that -- maybe other consumer products.

So for -- the existing regulations provides that there's no exposure for purposes of Prop 65, if the chemical is naturally occurring in a food. There's some -- I didn't quote the entire regulation here, but there's some nuances to the reg. There's a difference in the way things are treated, depending on whether they're a constituent of the food, or a plant, or if they're a contaminate in the food. For purposes of this regulation that we're talking about today, we're talking about contaminants. Both arsenic and lead are contaminants in foods.

The regulation excludes chemicals that are present in a food due to known human activity. It also talks about excluding chemicals that are present in the food that -- where they are just present because of absorption or accumulation from the location where the food is grown, which is important when we're talking about

lead and arsenic.

And then it also talks in subsection (a)(2) about the possibility of allowing for naturally occurring background levels of chemicals if there's reliable regional data.

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CHIEF COUNSEL MONAHAN-CUMMINGS: Now, in practice, the naturally occurring regulation has been very difficult to apply in the real world. And it's been litigated in a number of different enforcement cases. And to my knowledge, it's only been successfully proven in one case.

So it's fairly clear that there are chemicals that are naturally present in food. Those same chemicals can be present through both human activity and through natural processes. And it's very -- often very difficult to differentiate between what's naturally occurring and what's there because of human action at some point in time. And so it's become clear that guidance is needed in this area.

I'm aware that there is a fair amount of interest in trying to expand the reach of the naturally occurring exemption, if you want to call it that. And this -- what I want to make clear is that this is our -- this is the concept for a particular issue. And we know that there's

a lot of other issues that are related to the naturally occurring regulation, and that those need to be addressed also. There's also other chemicals that are naturally occurring besides lead and arsenic. There's also other foods besides rice and leafy green vegetables, for example.

And so we're aware that there are limitations on the proposal that we're making, but we have to start somewhere. And so we've decided that based on kind of the, I guess, existing situation, both from the litigation side and from requests for guidance from our side, that maybe this is a good place to start in terms of looking at lead and arsenic.

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CHIEF COUNSEL MONAHAN-CUMMINGS: Okay. So the new regulation basically would adopt a new section in the existing regulations that would follow the current naturally occurring section. And it would create kind of a place for adoption of safe harbor levels that would be concentrations of chemicals in foods that would be considered background.

As I mentioned, the first two are lead and arsenic. And we're -- we would be establishing levels for certain types of plants that -- and what would happen is that you could use, as a defense, you could subtract that

level from the total amount of say lead or arsenic in your product prior to comparing that level or that exposure to a safe harbor level for that particular chemical.

And again, our -- assuming that this process is successful, we are anticipating adopting additional levels for other chemicals or other products in the future.

So with that, I would turn this over to Melanie, so she can explain the concept in more detail

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DR. MARTY: Good afternoon. So one might think how can lead occur naturally in foods. And as Carol mentioned earlier, lead is a naturally occurring element in soil. And it is taken up into plant tissues when the soil -- from the soil when the plant is growing.

It's also a soil contaminant due to human activity. For example, soil concentrations have increased due to the use of tetraethyl lead in gasoline. So that can be viewed as more of a widespread contamination, since it was used everywhere.

It also is increased from use of lead-based paint, for example, on the outside of a house. When that paint peels off, it contaminates the soil around the house. It's a little more localized in terms of the extent of contamination from a single source.

There's also mining and smelting activities that

have occurred, battery recycling activities that have occurred that can increase soil concentrations of lead. It's a little more localized than you would anticipate or that you would think about use of tetraethyl lead in gasoline, but it can disperse a little more if it's airborne, for example, from a smelting activity.

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DR. MARTY: We wanted to try to get at -- get a handle on what is really naturally occurring in food. So we approached it in a couple of different ways. One way was to just start looking at lead concentrations in soil. So we evaluated studies that were available, a couple of pretty good large studies.

In 1978, USDA did a soil conservation service study looking across the United States just for a bunch of metals, including lead, on what is sort of typical of surface soils. So in agricultural areas, this particular study focused on agricultural areas, across the U.S. the average was about 12.3 parts per million.

In 2013, the U.S. Geologic Survey published a report. They weren't necessarily focusing on agricultural areas, but they did take some of the samples in agricultural areas. And this was a very large study. They had more than 4,800 Samples. And across the U.S., the mean background level for topsoil, which is

essentially the first five or so centimeters in this study, was 14.8 parts per million. And then the A horizon, which is the next deepest level, think of it that way. It's a combination of the geologic sources, so this parent material, as well as sources that have occurred over time of soil, so decomposing plants and whathaveyou.

So that's the A Horizon. And that across the U.S. averaged about 18 parts per million. So that's where you might expect roots to be, for example. And the sampling was completed in 2010, so those data are, relatively speaking, relevant for current times.

Both of these studies found that California had -- California soils had lower than average lead levels compared to some of the other states.

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DR. MARTY: The California Department of Food and Ag also conducted a study. So there are a couple of studies that I'm talking about.

First, they had archived samples, sample size of 50, that -- from uncultivated locations that they took in 1967. And in 2001, they went back and sampled from the same areas at the same depths just to see if there was a time trend for lead in soil. And you can see from the table that the range overlaps. It looks like it's slightly increased over time at the same depths, but it's

unclear whether those are statistically significant increases.

Nonetheless, the increases could be from leaded gasoline, which was still in use in the early part between 1967 and 2001, and other industrial activities, the increasing urbanization in California.

So in the same study, they took, in 2001, pairs of samples collected in cultivated locations, so these are agricultural soils, to compare concentrations from different depths. So one depth is about 20 centimeters. Sort of at the root zone, if you can think of it that way, and then deeper looking for parent material, which is basically geologic source.

So they took pairs of samples in several locations in seven different areas. Three of those seven locations showed a slight increase in the concentration in the shallower soil of lead relative to the deeper soil, the baseline soil. So that may reflect deposition from human activity. But the remaining four areas, which were actually largely agricultural didn't really show a difference by depth of soil.

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DR. MARTY: We also wanted to look at studies that had measured lead in food. So one of the common studies is the Market Basket Survey, which you probably

have heard about. It's the U.S. FDA's total diet study. In these studies, they collect foods throughout the U.S. and analyze them for nutrient content but also for contaminants.

We also took a look at the peer-reviewed literature. There are a number of studies where it controlled exposures. You can think of it that way. So they're growing plants basically in a lab or a greenhouse setting in different -- in soils with different concentrations of lead. So in most of these studies they're trying to look at if you have highly contaminated soil, what happens to the plant -- the concentrations in the plant. But a lot of these studies used uncontaminated control soils. So the uncontaminated control soils were -- had lead concentrations between about 3 and 22 ppm, which is about what you see if you look around the U.S. and in California.

So we took a look at those to see if we could figure out a way to estimate lead concentrations in crops based on the lead concentrations in the soil.

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DR. MARTY: Well, it turns out there really is a lot of factors that influence the ability of a crop to accumulate lead and to translocate it to the edible parts. And some of these include climate, the soil type, things

like the chemistry in the soil, the pH of the soil, whether it's sandy or loam and all those other characteristics of soil, and also the genotype of the plant. So the same kind of crop, but a different strain, you would get different results.

And then crop management practices influence. So we also looked across studies, and it was clear that the relationship between the lead concentration in the soil in these controlled experiments and lead uptake by the crops was not linear always.

So this complicates trying to use soil lead data to figure out what a background lead concentration might be in a crop. So we tried that using uptake factors, and we were predicting crop lead levels that were higher values than what is being measured in food in the total diet study.

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DR. MARTY: So we decided for this purpose to use the total diet study data to help inform us of the background lead levels in fresh food. So I have to say only about five percent of the fresh food samples had detectable levels of lead. So we ended up saying, okay, we're going to use the limit of detection as the starting point to derive background lead levels in foods, except for leafy green vegetables. And the reason that's -- we

didn't want to do it for leafy greens is they actually had more frequent detections than other categories of vegetables and higher lead levels.

So in that case for leafy greens we used the average of the detections in the total diet study as the starting point.

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DR. MARTY: So we thought, okay, well, how do we get a handle on accounting for the amount of naturally occurring lead versus lead that has been added over decades because of human activity? So what we did is we went back to the CDFA study where they measured in the same place but at different depths. And we made the assumption that the deeper soils were the geologic origin of lead, and the upper level soils would be where you might see human contributions to lead in the upper level soils.

So we ratioed the baseline to upper levels in the soils to get a ratio of 0.88. So that's the average of the ratios from that study where you're looking at the lower -- the deeper levels versus the upper levels.

So then in this scenario, the naturally occurring concentration then is the limit of detection from the total diet study times 0.88 to allow for -- to accommodate this concept that humans have also contributed to the lead

in the soil. So that would be the naturally occurring concentration.

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DR. MARTY: So this table shows the naturally occurring background lead levels in fresh foods. The first column is the food category so you can see that they're lumped by the total diet study categories. The limit of detection is shown in the second column. But the leafy vegetables there, that's actually -- that 0.01 ppm is the average of the detections. So that was the starting point for the leafy vegetables. Then times the correction factor, which is that middle column gives you the naturally occurring background lead level in that food category.

So for most foods, it's pretty much the same, because it's based on the limit of detection, right? So it's 0.0062 ppm, or 6 ppb. And for leafy vegetables, it's a bit higher.

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DR. MARTY: Okay. So how would you have used this result? So the background concentration for specific categories of food would be subtracted from the concentration in the unprocessed food that's measured. So, for example, if you have a sample of a non-leafy vegetable, it's measured to have 0.01 parts per million

lead. The concentration that would be considered not naturally occurring would be that 0.01 ppm measured level, minus the naturally occurring background. And in this example, it turns out to be 0.0038 ppm would then be considered not naturally occurring for the purposes of Prop 65.

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DR. MARTY: So I'm going to switch gears now to arsenic. We pretty much tried the same approaches. Why is arsenic found in food? Again, it's a naturally occurring element in the soil. It's taken up into plant tissues in varying amounts during growth of the plant. We evaluated sources of information on regional soil concentrations. There's, of course, the geologic processes from erosion and what have you, so you end up with arsenic in the soil naturally.

Sometimes groundwater contains arsenic. And if you're irrigating with the groundwater, then there's a source of arsenic for the plants.

There are, of course, a number of anthropogenic or man-made sources. One of them is use of pesticides containing arsenic, which isn't done anymore. But it was done quite a bit several decades ago, particularly in orchards and cotton.

We also can see from sources in literature that

there could be increased soil concentrations from mining and smelting and use of arsenic treated woods. So there are a number of wood preservatives that contain arsenic that were used in the past, and I believe some are still used. So you can look at the arsenic concentrations in soil underneath those structures and they're higher than the surrounding area.

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DR. MARTY: Again, we looked at studies looking at arsenic concentrations in soil, looking at the CDFA study that I had mentioned for lead where they collected duplicate samples. They had archived samples from 1967. They went back in 2001 and took from uncultivated locations in 2001, and looked across time to see if the arsenic levels were about the same or were they different.

And in this case, it looks like they're a little bit lower than they used to be in 1967. But again, I'm not sure that's statistically significant.

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DR. MARTY: One of the studies that we focused in on is the USGS 2013 study. And we looked specifically at arsenic in soils in California counties that grow rice. So that's what this table is all about. You can see the county on the left, the number of samples. So you can see that some of them are pretty small.

And then they -- in this study, they looked at different depths topsoil and the A Horizon and then the C Horizon, which is the parent material from geologic origins. So that's the rocky stuff, not the topsoil.

And notably, the arsenic in soil in California rice counties is pretty similar to the national averages. And if you look across the columns, you don't see a whole lot of difference between Horizon C, which is representative of geologic material, from whence the soil was derived, through Horizon A in the topsoil. There's not a lot of difference.

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DR. MARTY: We know that uptake of arsenic in rice plants is just unavoidable. The plant just does it. It varies by the type of rice, the soil concentration, and then other factors similar to lead, so the type of soil, the pH, the how you manage the soil. We do note that higher soil levels lead to greater uptake in a accumulation of arsenic in the rice plant. But again, it's not linear, and there's a lot of factors that influence that.

The arsenic levels are higher in the bran, so that's the outer coating of the rice grain. So brown rice has higher arsenic levels than white rice. And the white rice that's where that little bran coating is removed.

Both inorganic and organic forms of arsenic occur in rice, but it's the inorganic arsenic that's listed under Prop 65, and it is widely viewed as more toxic than the organic arsenic compounds.

So arsenic is listed as a carcinogen -- inorganic arsenic compounds under Prop 65. And inorganic oxides of arsenic are listed as reproductive toxicants.

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DR. MARTY: We took a look at information that we could get our hands on for historical arsenical pesticide use in California to help us figure out is there -- some of the arsenic not just geologic in origin, but was contributed by use of arsenical pesticides.

So it's notable that the CDFA study did not indicate any areas of high arsenic contamination when they looked at crop land regions. So it didn't appear that arsenical pesticide use was contributing anything.

We also looked at publicly available data sources for historical land use. So where were different crops grown over time in California? And we were trying to see if crops that had arsenical pesticide applications done in the past, if the soil there had more arsenic, and if those were the same areas that -- where we're growing rice now?

So mapping it out looks like less than five percent of recent rice growing areas -- recent being 1985

to 2010 or '11 -- overlapped with areas where crops had been grown with potential arsenical use. And looking across all the data, it just appears that the potential contribution of arsenic from arsenical pesticides to soil levels in areas where rice is grown in California appears minimal.

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DR. MARTY: So we then turned to looking at studies that measured arsenic in rice. We focused in on a couple of studies. One is a U.S. FDA study published in 2013. They looked at inorganic arsenic in rice and rice products. They sampled brown and white rice from four rice-producing states, Arkansas, California, Louisiana, and Texas.

We also looked at studies done by UC Riverside commissioned by the California Rice Commission. And they sampled in 2012 and 2013 again brown and white rice samples. This time from six different states, so they added Mississippi and Missouri. And that study analyzed for both total and inorganic arsenic levels.

And then we looked at the peer-reviewed literature to try to see if we could look at controlled growing scenarios where they had different levels of arsenic in the soil and tried to see what happened in the rice plant.

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DR. MARTY: Okay. So using uptake factors derived from those controlled exposure studies, we ended up estimating again higher arsenic values than are being measured in the studies measuring the rice. So we decided to go with the studies that measured arsenic in the rice.

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DR. MARTY: Again, the majority of arsenic in California soil and rice growing areas appears that it's naturally occurring. So our pre-regulatory proposal then is to use the mean values of inorganic arsenic in white and brown California grown rice as the safe harbor for naturally occurring levels.

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DR. MARTY: This table shows what those values are. So we have the rice type on the one column, brown and white, the samples sizes, and then the concentration of inorganic arsenic -- and don't let the units fool you. Milligrams per kilogram soil that's the same as parts per million.

So the mean value for brown rice is 0.13 parts per million. The mean value for white rice is 0.057 or 0.06 rounded up to two significant digits.

It's notable that the average of inorganic arsenic in U.S. grown rice across studies is just a little

bit higher. So whether that's really a difference or not, it's not clear, but it's really not that different, 0.15 versus 0.13, 0.08 versus 0.06.

So then our pre-regulatory proposal is that naturally occurring inorganic arsenic levels for California rice apply to all rice, independent of the location of where it was grown. And the safe harbor naturally occurring rice concentrations for white rice are 60 parts per billion. That's the same thing as 0.06 parts per million. And for brown rice, it's 130 parts per billion, the same thing as 0.13 parts per million.

That's all I have.

MS. MONAGHAN: Okay. Do we have -- I have no blue cards. Does anyone wish to speak?

We do have a blue card. So Cynthia Cory.

MS. CORY: Good afternoon. Cynthia Cory, California Farm Bureau.

I first wanted to thank OEHHA staff for finally attempting to provide us some clarification. For many, many years as most of you know that we've worked with, that this has been something that we've been asking for some help on, and struggling with. So we thank you for finally getting to this point.

Our struggle is that it's hard to understand how this naturally occurring proposal fits, because at the

same time we're looking at this, we've got these other moving parts.

You're also talking about changing the geometric -- from the geometric mean, you're not going to let us average across lots, and you're lowering the lead MADL by 60 percent. So it is really hard for us to look -- just look at the -- what's contained in this naturally occurring and figure out how these other parts will impact it.

So we have probably a lot of questions which we will detail in our written comments. But I just wanted to like tee up some of the things that we've been questioning amongst ourselves. And one of them has to do with testing, when it will occur? You've got -- these are raw products that are teed up here, but a lot of his raw products goes to process products. What does that mean. When you've got these raw products -- you all know farm to fork is where we're supposed to be going these days. That's really fast. That's a really fast process.

So you want your food as fresh as possible. So how, and how much, how is that sampling all supposed to occur? That's something that we need some answers about.

We're glad to hear from what -- Carol's comments in the PowerPoint that you're talking about this being more than what you have here with the lead and the arsenic

in the rice, and the few things that you've listed there. But if that is the case, it would be nice to have a little bit more understanding about that process, and making sure that that's indicated as we go forward.

We've got a lot more that we need to understand about this. I just wanted to make sure that you know those few points. We've got a lot on our plates these days, not just with Prop 65, but there's a few things going on at CalEPA. And so we hope you appreciate that we want to spend as much time reviewing this as possible, and we want to work with you closely on it.

MS. MONAGHAN: Do you want to respond at all?

No. I'm sorry, I'm talking to Melanie and Lauren.

Okay. Next Anthony -- Samson.

MS. MONAGHAN: Thank you.

MR. SAMSON: Anthony Samson with the California Chamber of Commerce.

My comments are very similar to those of Cynthia's. And I want to again thank OEHHA for attempting to establish a framework for a more workable naturally occurring exemption, which, as we all know, has been long viewed as an important tool, but one with virtually no practical utility.

Again, similar to what Cynthia mentioned, the

concern with the proposal as a stand-alone proposal, is that it's so limited in its application that we feel like giving it a broader application would be much more appropriate and we're happy to work with you to applying this similar concept to background levels to a broader range of commodities.

Then when moving away from that and looking at this combined with the other proposals, the lead MADL, the barring averaging for reproductive toxicants, barring lot averaging, and then requiring use of the arithmetic mean, those taken and combined, it is very difficult to work on this issue productively combined with those, because it's difficult to understand whether or not it will, in fact, have any practical utility when combined with those proposals. Whereas, a stand-alone proposal I think that there is some benefit.

So we look forward to continue working with you on this. Again, I think the concept of background levels is very much appreciated, and we look forward to working with you on this issue moving forward.

Thanks.

MS. MONAGHAN: Okay. Trent Norris.

MR. NORRIS: Good afternoon. Trent Norris with the California Chamber of Commerce and a coalition of other trade associations.

I wanted to echo the comments of the Farm Bureau about how happy the agricultural and food industry is that OEHHA has taken this up. This is something that folks have asked for for years, given how difficult it is to use the current naturally occurring regulation and actually prove that something is indeed at the level of a chemical found in the product is indeed naturally occurring.

It's happened in the tuna case. And beyond that, a great deal of money has been spent in litigation on these issues, but you're essentially proving a negative. You have to prove that the level of the chemical that's present in the product was not put there through any human interaction. And that's extraordinarily difficult to do as the cases show.

There are lots and lots of food cases under Prop 65. That shouldn't be any surprise, but everything from grilled chicken, to hamburgers, to noodle-based soup, to rice, now cookies, candy, fruit and fruit juice in the Beechnut case, of course, snack foods, potato chips, french fries, cereal, bars, shakes, powders we could go on and on. And there's been a great deal of litigation resulting from this because food companies do not want to put a warning on the product. It's very different from spray paint, for instance.

So, as a result, having a naturally occurring

regulation that's workable is very important, so that consumers don't get extra warnings, and so that products are not taken off the shelf or off the market that affect people's dietary choices.

We've been concerned for a long time that OEHHA is not an agency that has deep expertise in food. OEHHA has a great deal of expertise in many, many things, but not so much food. And we've encouraged OEHHA to work closely with the California Department of Food and Agriculture when it's undertaking actions that affect food.

We're pleased to see that there's been some interaction on this issue, and we would encourage that consistent with the Memorandum of Agreement between the two agencies that's now a few years old. But there are lots of other issues coming involving food.

The International Agency for Research on Cancer just yesterday closed its session, I believe, on red meat, and deciding whether red meat causes cancer and should be listed as a carcinogen, under the IARC process.

If that were to occur, according to OEHHA's interpretation of the Labor Code listing mechanism red meat would be listed as a carcinogen under Proposition 65.

Coffee is coming next summer, by the way. So it's very important that OEHHA undertake these issues and

be looking ahead at what may be coming down the pike in and all of this, so that we can figure it out. Now, with respect to this particular proposal, we will have some questions in our ultimate comments about why, for instance, chocolate and calcium and other minerals are not included, because there are consensus levels, which have been developed through scientific review, actually very similar to what OEHHA has undertaken taken here with respect to those specific elements, which are found in many, many food products, including a lot of dietary supplements.

And they're memorialized in number of consent judgments that have been approved by courts that these Attorney General's office has either been a party to or has reviewed and commented on.

And then in addition, there are questions here -- definitional questions about what is a vegetable. And drawing the lines between leafy and non-leafy vegetables, for instance, may be an issue as well that we'll be presenting comments on.

But, in essence, you know, we're very heartened that OEHHA is undertaking this. The fact that it's in conjunction with so many other moving parts makes it quite complicated, but we look forward to working with the agency on this, and also very much appreciate the comments

that this is just a start of a longer process with respect to other chemicals and other food products and ingredients.

Thank you.

CHIEF COUNSEL MONAHAN-CUMMINGS: Excuse me, Trent, just a quick question. This is Carol. When you submit your comments, if you could also submit copies of whatever consent judgments you would like to see us take a look at. Given that we don't get copies of those on a routine basis, we might not be aware of the ones that you want us to look. So if you could do that, that would be great.

MR. NORRIS: I'd be happy to do that.

CHIEF COUNSEL MONAHAN-CUMMINGS: Thank you.

MS. MONAGHAN: Okay. Matthew Allen.

MR. ALLEN: Good afternoon. Matthew Allen, Western Growers Association. We also appreciate the time and effort that's been put into this workshop on naturally occurring. We're also getting our arms around all the different moving parts here, and we will have ongoing questions regarding setting the background levels and how that comports to the moving pieces with averaging lot sizes, and I'm granted not a Prop 65 or Prop 65 expert or a scientist, so we're spending some extra time on that.

One thing that I would note that's of concern in

the discussion of the back -- setting of the background levels is it seems to be a bright line. And, you know, we do find that there are natural variances that do occur even within fields. And so that's a concern for our growers.

You know, what's the appropriate way to test that's reasonable? And if it's truly naturally occurring, then it would be naturally occurring across the field, even if there may be a spike in someway. So how do we actually address that, and we're trying to figure out the best way to do so, and then how that would fit within kind of the direction you guys are headed.

All right. Thank you.

MS. MONAGHAN: And Eric Somers.

Is there anyone else who wishes to speak? I have blank cards.

MR. SOMERS: Eric Comers with the Lexington Law Group.

I just had a couple of questions that I think would help inform our comments. Things that were just a little unclear from the proposed draft that I'd like to ask now, if that's okay?

Can you talk just for a second about the unprocessed versus processed, what happens when an unprocessed food is incorporated into a processed food?

For instance, sugarcane is made into molasses. Does the safe harbor follow it? It's a little unclear as to how that would work.

CHIEF COUNSEL MONAHAN-CUMMINGS: Well, I think the intent of the naturally occurring regulation overall would be the same when we adopt these numbers. And that is that the intent is to look at natural foods kind of in their natural state, and not take -- not something that has been processed so much that you're not really able to parse that out anymore.

And so what you're looking at would be -- and that's why we're doing it kind of crop by crop or close to that, because, you know, if you're looking at white rice and brown rice, there's a fairly limited amount of processing that goes on in that. Now, if you're looking at a product that includes brown rice and white rice, then I would say that the defense is going to have to show that that amount came from that rice not some other thing that happened once the food was processed and made into some other meal, for example.

But the concept is that you'd be looking at what is the level in the unprocessed food, subtract out the safe harbor level, if you will, concentration, and then the rest of it's considered the result of a human activity. So you really need to be looking at the

unprocessed food at that point.

MR. SOMERS: Okay. That's helpful. Thanks.

And then it looked to me the way that the proposed actual addition to the reg was drafted that it didn't change existing regs, but was added on. Do you need to comply with the rest of the existing regs? Do you need good agricultural practices and good manufacturing practices and lowest level feasible in order to partake of the safe harbor?

CHIEF COUNSEL MONAHAN-CUMMINGS: Well, we haven't determined yet whether or not this section would go in the existing regulation or outside of it. But they would be -- the proposed regulation, as it was drafted, at least in our minds, or my mind, is that it's adding a little definition to one part of the section of the existing regulation. So you have to take it together.

So it's -- you would be looking at the chemical in a food. You could apply this level, but then you're still in the existing naturally occurring regulation. So if you're talking about a contaminant such as lead or arsenic as a contaminant, then the human derived part of that needs to be reduced to the lowest level feasible. But you could still subtract the natural background level first.

MR. SOMERS: Regardless of whether you were

applying good manufacturing practices or good agricultural practices?

CHIEF COUNSEL MONAHAN-CUMMINGS: I think so.

MR. SOMERS: So even if the naturally occurring level was below the safe harbor and you were not applying good agricultural programs or good manufacturing practices, you would potentially get the benefit of that?

CHIEF COUNSEL MONAHAN-CUMMINGS: As drafted right now, yeah. You might want to mention that in your comments. We'll look at it some more.

MR. SOMERS: Okay. And then with arsenic in rice, it seems like a lot of work has been put in on that. Is there any move to actually do a MADL for arsenic?

ACTING DIRECTOR ZEISE: We have a -- so, yes, there's a lot of work looking at arsenic in rice. And some years ago we did have a draft MADL. There's a lot of studies that have been developed since then, and many, many things on our plate actually.

And so in terms of resources, we're not currently working on a MADL for arsenic. We just, you know, don't -- are focusing our attention on other things.

MR. SOMERS: Okay. And then just I guess on the comments that I would note that it looks like, just a rough calculation, that the arsenic in rice level to us would look like a very high naturally occurring, about 10

micrograms in a serving size of 79 grams, which is a big number is my comment.

Thank you.

MS. MONAGHAN: Do we have other questions, concerns, comments?

Great. Then Lauren, I'm going to -- was there a comment in the back. You need to come up to the microphone, and please let us know your name.

MR. RIEDEL: Karl Riedel with the Natural Products Association. I find it interesting that based on the presentation of the science between the levels of these toxic chemicals in certain types of foods versus other types of foods, it will be very interesting down the road how the health educators in our country are going to be able to explain to people that we want you to eat brown rice because it's healthier than white rice, but you can't because it's got too much lead, or we want you to eat more leafy green vegetables, but we can't because it's got lead.

So it will be very ironic to see how that's going to affect your thinking on these levels that you come up.

Thank you.

ACTING DIRECTOR ZEISE: Thank you.

MS. MONAGHAN: Okay. Other questions, concerns, comments?

Now, I will turn it over to you.

ACTING DIRECTOR ZEISE: Thank you, Jodie.

Well, again, thank you for all your input on this. We are really looking forward to hearing your ideas on our regulatory concept. If you have some additional ideas, we really would look forward to hearing those laid -- and seeing them laid out.

I think our written comments are due November 12th, 2015. And again, you can see on our slide Monet Vela is the person to submit comments to. Again, we do prefer comments submitted electronically. It's just easier for us, but we'll happily also take written comments in hard copy.

So the next step is to think very hard about this, take in all the comments, and move towards a regulatory proposal. We don't have an exact timeline for that, at this point, but we do intend to steadily move forward and work on this and put this out as a regulatory proposal.

I want to thank again -- and, as part of that, there will be ample opportunity for public comment. There will be a hearing. We'll follow, of course, the APA process.

So thank you again, everyone, for participating in this workshop. We hope to see some of -- or as many of

you as possible on Monday, where we'll talk about the averaging concentrations in food in our pre-regulatory proposal for average consumer.

Thanks again to our staff at OEHHA and to Jodie for a very nice job facilitating this workshop.

Thank you.

(Thereupon the workshop concluded at 1:57 PM)

C E R T I F I C A T E O F R E P O R T E R

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, do hereby certify:

That I am a disinterested person herein; that the foregoing California Office of Environmental Health Hazard Assessment workshop was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California;

That the said proceedings was taken before me, in shorthand writing, and was thereafter transcribed, under my direction, by computer-assisted transcription.

I further certify that I am not of counsel or attorney for any of the parties to said workshops nor in any way interested in the outcome of said workshops.

IN WITNESS WHEREOF, I have hereunto set my hand this 26th day of October, 2015.

JAMES F. PETERS, CSR
Certified Shorthand Reporter
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