PUBLIC HEARING

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

In the matter of:
)
The Center for Environmental Health Petition Requesting Repeal or Amendment of the Safe Harbor level for Lead
)

CALEPA HEADQUARTERS

COASTAL HEARING ROOM

1001 I STREET

SACRAMENTO, CALIFORNIA

WEDNESDAY, OCTOBER 14, 2015

10:04 A.M.

JAMES F. PETERS, CSR
CERTIFIED SHORTHAND REPORTER
LICENSE NUMBER 10063

A P P E A R A N C E S

STAFF:

Dr. Lauren Zeise, Acting Director

Dr. Martha Sandy, Chief, Reproductive and Cancer Hazard Assessment Branch

Ms. Carol Monahan-Cummings, Chief Counsel

FACILITATOR:

Ms. Jodie Monaghan, UC Davis

ALSO PRESENT:

Ms. Caroline Cox, Center for Environmental Health

Mr. Mike Easter, EnSIGHT

Mr. Patrick Elie, Outdoor Pro Shop and American Sportfishing Association

Mr. Jon Kendrick, Locke Lord, Independent Cosmetic Manufacturers and Distributors(ICMAD)

Dr. Mike Lakin, EnSIGHT

Mr. Trent Norris, California Chamber of Commerce

Mr. Alan Olson, Society of Glass Decorators

Mr. David Roe

Mr. Anthony Samson, California Chamber of Commerce

Mr. Eric Somers, Lexington Law Group

I N D E X

P R O C E E D I N G S

ACTING DIRECTOR ZEISE: Good morning. I'm Lauren Zeise. I'm Acting Director for the Office of Environmental Health Hazard Assessment, or OEHHA. And I'd like to welcome people both in the -- here in the room with us and also people that are listening on-line on our webcast.

So this is the first meeting of four meetings to address -- to present pre-regulatory concepts to either update and/or clarify our Proposition 65 regulations. So with me at the table is -- to my left is Dr. Martha Sandy, Branch Chief of the Reproductive and Cancer Hazard Assessment Branch. To my right is Carol Monahan, who is our Chief Counsel. And also this meeting is being facilitated. We have -- the meeting is being facilitated by Jodie Monaghan of UC Davis extension.

Jodie, would you like to stand up.

MS. MONAGHAN: Good morning. And, by the way, it's Monaghan. No relation to Carol.

(Laughter.)

ACTING DIRECTOR ZEISE: Okay. So I have some more introductory remarks, and then I'll turn to you, Jodie, to fill us in.

(Thereupon an overhead presentation was presented as follows.)

ACTING DIRECTOR ZEISE: And it looks like we also have Carol's slides, so I think we'll stick with our agenda for a minute. It looked like we were having a little bit of difficulty pulling up Carol's slides.

So I'd also like to introduce staff that you can give your blue speakers cards to. So Monet Vela, could you raise your hand, and Esther Barajas-Ochoa. So if you wish to speak, if you could be sure to give them your cards -- your speakers cards.

So today, what we're doing is considering the first -- again, the first of four pre-regulatory concepts. We're also considering a petition received from the Center for Environmental Health asking OEHHA -- or petitioning OEHHA to either repeal or revise our maximum allowable dose level for lead. So today we're looking at that.

This afternoon, we're looking at a safe harbor to add a section to our regulation that provides -- lays out naturally occurring safe harbor concentrations for naturally occurring chemicals in food. So that's this afternoon.

And then on next Monday, we'll also be looking at some clarifying pre-regulatory proposals for clarifying levels of concentrations of chemicals in food, as well as a pre-regulatory concept looking at the whole issue of what we mean by average consumer.

So today, what our pre-regulatory idea on lead is actually a little multi-faceted. One thing that we're doing is coming up with a concept for dividing -- putting a little bit more structure into our MADL regulation, which would be to have a section in the reg that we -- that contains maximal single day levels. And then another section of the reg, which would allow for a variety of maximal levels, depending on the frequency of exposure. We could also add additional chemicals for which you would average. So that's one of the pieces of the regulation. The other, of course, is this different approach to looking at maximal levels for lead.

So as we start, we're going to first hear from Jodie about some process issues. And then we'll be hearing the legal context from Carol Monahan-Cummings. We'll also hear from Caroline Cox about the CEH petition, and then Dr. Martha Sandy on what our pre- -- more details on our pre-reg proposal.

So what we would like to do is hear from all of you today who wish to speak. We see that there are several who have some PowerPoints. If you could please fill out the blue cards and make sure you get them to either Monet or Esther, so that we can be sure to divide up the time, so that we can hear from you all. We do have a maximum of five minutes for presentations. I hope we

can fit everyone. We want to allow time for everyone to speak, so we might ask some of you to shave a little bit of time off, if that's necessary.

But we also have a comment period for written comments. So what we'd like to hear is basically conceptual issues today. And then if you could lay out in detail, if you have specific proposals, if you could do that please in writing. That comment period closes on October 28th.

So this meeting is being webcast. And if you would like to invite or message some of your colleagues to watch it, I believe you can go to calepa.ca.gov. And all they have to do is click on the website button to hear the webcast. The meeting is also being transcribed, and the transcript will be made available to the public as soon as it is ready.

So we're looking forward to the full range of ideas and looking forward to hearing in writing more detail. And now I'll ask Carol -- Jodie -- sorry -- Jodie, who will be facilitating the meeting to tell us about some process issues.

Jodie.

MS. MONAGHAN: Thank you. So my name is Jodie Monaghan. I'm with UC Davis Collaboration Center. My role today is to work as a third-party neutral, but my job

is to make sure that you all have an opportunity to be heard before OEHHA.

I want to go over some quick housekeeping items. Bathrooms, for those of you who don't know, out the door, all the way down to your left. The -- as Lauren pointed out, we are being webcast. Emergency exits. Should there be any sort of emergency, out this door to your right, down the stairs, out the front door.

So I also want to just review some quick agreements, ground rules, whatever you choose to call them. I'm going to ask that you participate fully. If you choose to have side conversations, please take them outside so you're not disturbing other people who want to hear the speakers.

Is this really echoing a lot? Do we have any options?

Does this work any better. Can you hear me at all?

Okay. So I'm going to ask that you participate fully, give us your attention. If you have side conversations, please take them outside. You're going to hear differing points of view. I ask that you listen to them with curiosity, and open-mindedness, and respect.

Conversational courtesy, as I'm sure that we all adhere to. Respect time. We'll get to that in just a

moment. Please silence -- take a minute and silence all your electronic devices. And one thing we are going to ask that you hold all your questions. You're going to have a presentation from Carol, a presentation from CEH, and a presentation from Martha. Your questions then will be part of your public comments. So we are not opening it to clarifying questions of any sort. As you come up here with your public comment, that can be your opportunity to pose questions and make comments.

What I'd like to do real quick is how many people are considering speaking? Could you raise your hands?

(Hands raised.)

MS. MONAGHAN: So I have one, two, three, four, five, six, seven. Then, in that case, we're in great shape. We have hopefully 65 minutes for public comment, max of five minutes.

Let me just, for those of you who are speaking, you will see signs to tell you there's one minute left, 30 seconds left, time's up. When you see the time's up, I will ask you to finish your sentence, providing there are not 47 subordinate clauses to that sentence.

(Laughter.)

MS. MONAGHAN: And sit down. And the reason is just common courtesy. If you extend your time, you're going to cut into somebody else's. And I think, in

fairness, we want to make sure everyone has adequate time to speak.

So please be sure that you -- if you're going to speak, that you have filled out a speaker card and given it to Monet or Esther, one or the other. And as -- after the presentations, we'll get into the public comment.

So before I turn it over to Carol, any questions?

Great. Thank you.

CHIEF COUNSEL MONAHAN-CUMMINGS: Good morning. For this hearing, since we only have a limited amount of time, I'm going to assume a basic level of understanding of Prop 65. So if there's someone on the webcast or otherwise that has more questions about the underlying law, I'm happy to answer those off-line.

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CHIEF COUNSEL MONAHAN-CUMMINGS: Okay. I can see. So just a quick background here, the chemical or the substance lead was listed in -- under Prop 65 in 1987. And the basis for the listing changed in 2013. Both of those listings are based on the Labor Code listing. The first one was based on the labor code listing process, the second one on the formally required process, but on -- still based on -- sorry -- still based on OSHA regulations. And so it's a little bit unusual. But the

current basis for the listing of lead is still OSHA regulations. And so that becomes important when we are looking at a MADL.

The current MADL was adopted in 1989 by the Health and Welfare Agency, which was the precursor agency to OEHHA. It was one of the first MADLs that was adopted. The -- and so in July of 2015, we got a petition from the Center for Environmental Health asking for us to open a rule-making to either repeal or amend the existing MADL for lead. And we considered that, looked at the petition, looked at some other information, and decided to grant the petition. As part of that, we set today's hearing.

So in thinking about the -- a new lead MADL, we developed a pre-regulatory proposal that would actually adopt multiple MADLs for lead. And we'll explain -- Martha will, in some detail, about why we think that would be appropriate in this particular circumstance. And as Lauren mentioned, what we had to do was -- as part of that proposal is we are also proposing a couple of modifications to the existing regulations that accommodate the fact that we would be potentially establishing multiple MADLs for lead since all of our current MADLs, including the one that we have now for lead, was established as a single-day exposure limit. We have to modify the regulation in order to add the new section for

intermittent exposures.

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CHIEF COUNSEL MONAHAN-CUMMINGS: So it doesn't come up very frequently, but there is a provision in the Government Code that allows anyone to petition a regulatory agency to take a regulatory action. And so that's what has happened in this -- in this case, the Center for Environmental Health has filed a petition. We were required under the Government code, which is cited here, to respond within 30 days to decide whether or not we would grant the petition and set a hearing or deny the petition and give the reasons for denying it.

So as you can see, we granted the petition, set the hearing for today, and drafted a proposal based on our current thinking on how to adopt a new MADL or set of MADLs for lead.

So, at this point, I just wanted to make sure that to let you know that I've asked the court reporter to mark the CEH petition as an exhibit for this hearing. And I've also given him a set of the notice -- the proposed language -- or the potential language and the background document also to be marked and put in the record for the hearing today

(OEHHA Exhibits A and B marked for

identification.)

CHIEF COUNSEL MONAHAN-CUMMINGS: Other comments or written material that we receive, including the slides that you've given us -- for those of you that have given us slides for today, it will also be included in the record.

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CHIEF COUNSEL MONAHAN-CUMMINGS: Okay. Next slide. So just real briefly, there's -- the statutory basis for establishing safe harbor levels is in Health and Safety Code 25249.10. And it talks about the level that would have no observed effect -- observable effect, assuming 1,000 times the level in question, which is a term of art that was established in Prop 65. It's not repeated in other statutes, but this is the one that we need to use for Prop 65. And it also requires that any -- that level be based on evidence and standards of comparable scientific validity to the evidence and standards which form the basis of the listing.

And so that's why I mentioned earlier that it's important to know what the basis for the listing of lead is, and that is that it's been listed under the formally required mechanism, based on language required in the OSHA regulations.

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CHIEF COUNSEL MONAHAN-CUMMINGS: So what we -- or the Health and Welfare Agency did many years ago is establish regulations to show how an individual or business could do a quantitative risk assessment for a particular chemical that may be on the list and establish a MADL. Our office also adopts MADLs, and we use the same procedures as are set out in the regulation. And I'm not going to read it word for word, but it's set out here.

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CHIEF COUNSEL MONAHAN-CUMMINGS: Our regulations do give general guidance for establishing the MADLs, including using studies that produce the same effect as the listing, using the lowest no observed effect level and/or the most sensitive study, looking at epi evidence where it's available, looking at animal studies where they are available. There's a number of defaults that are established in the regulation. And the regulation allows for levels to be established for intermittent exposures. But as I mentioned earlier, we haven't adopted any of those in the past. So this is our first foray into that area. And so you'll hear more about the basis for that from Martha.

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CHIEF COUNSEL MONAHAN-CUMMINGS: So at this point, I'm just going to turn the microphone over to Caroline Cox from the Center for Environmental Health, who will be making a presentation on the petition.

Caroline. You want to come up here.

(Thereupon an overhead presentation was presented as follows.)

MS. COX: Good morning, everyone. Can you hear me?

Okay. My name is Caroline Cox, and I'm the Research Director at the Center for Environmental Health. And OEHHA asked me to speak just for a few minutes to sort of explain our petition and why we submitted it.

You can go to the next slide.

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MS. COX: Okay. Can I advance it?

So the Center for Environmental Health is a nonprofit organization. Our main office is in Oakland. We also have an office in New York. CEH started in 1996, so we're getting close to our 20th anniversary, which is really exciting. And basically, ever since the organization started, one of our important objectives has been to reduce people's exposure to lead. So maybe a few words about why we've been working on that for so long.

So first, our overall mission is to protect families from toxic chemicals. Lead kind of rose to the top for a couple of reasons. One is that it's a chemical that we like to say is stunningly toxic. There's just so many adverse health effects that have been linked to lead exposure. And as the science has improved over the last decades, we've found problems caused by lead exposure in smaller and smaller amounts of exposure.

And I think the other thing that's really important about lead for us is that many toxic chemicals are things that, in the environment, due to, you know, sunlight, or microbial action, or whatever break down. Lead doesn't break down. Lead is always lead. It's always here. So there's an ongoing need to protect families from lead exposure.

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MS. COX: So we were concerned about the existing safe harbor level for lead. It was set using a 1978 occupational safety and health regulation. So what that means is that the science on which the safe harbor level is based is really old, at least 35 years old. And like I mentioned before, there's a lot of new science. So we felt like it was important to ask OEHHA to take a look at the safe harbor level using current science.

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MS. COX: And one thing that OEHHA itself had stated many, many years ago was that even when they did set the safe -- the existing safe harbor level back in 1989, they knew that it was too high. So even based on the science at that time, the safe harbor level was really not appropriate

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MS. COX: This is a graph from the CDC, Centers for Disease Control and Prevention. And I think it illustrates really well what lead science has learned over the last few decades. So starting in 1960 or 1970, the amount of lead exposure that is recognized by the CDC to cause a problem has just steadily gone down, down, down, down. So any safe harbor level set based on 1970's science seems clearly like it's going to be out of date and in need of revision.

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MS. COX: And then the second part of the petition had to do with exposures that occur every day. I think the shorthand for that is a single-day exposure, as opposed to intermittent exposures. And again, OEHHA had had a long-standing policy that wasn't formally adopted, but that the safe harbor level it was appropriate to look at a single-day exposure. And so we asked OEHHA in the petition to make that a formal policy.

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MS. COX: So just to kind of sum up the petition, we basically asked for two things. One, repeal or amend the existing safe harbor level, so that it would be based on current science; and, second, clarify that the safe harbor level is a single-day exposure, so that there would be a formal policy stating that.

So that's, in brief, what the petition is. I don't -- do I get to answer questions or --

MS. MONAGHAN: No.

MS. COX: Yeah, save your questions.

ACTING DIRECTOR ZEISE: Okay, Martha. Dr. Martha Sandy will now present our pre-regulatory proposal.

(Thereupon an overhead presentation was presented as follows.)

DR. SANDY: Good morning.

So as Lauren said, I will be presenting our pre-regulatory proposal for possible amendments to section 25805, specific regulatory levels, chemicals causing reproductive toxicity.

The pre-regulatory proposal for amendments to section 25805 would do three things.

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DR. SANDY: The proposal for 25805(b)(1) clarifies that the MADLs adopted in this section were

established as a single-day exposure limit. The proposal would add a new subsection 25805(b)(2) with MADLs for certain chemicals for intermittent exposures. And the proposal would repeal and replace the existing MADL for lead with MADLs in subsection 25805(b)(2).

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DR. SANDY: The proposed amendments would read as follows:

Section 25805(b), "Maximal allowable dose levels are provided in this section". Add then (1), "The exposure levels set forth below represent the total exposure which a person in the course of doing business may knowingly and intentionally cause to any individual on any single day and be exempt from the warning requirement pursuant to Health and Safety Code section 25249.10".

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DR. SANDY: Section 25805(b)(2), "The exposure levels set forth below represent the exposures which a person in the course of doing business may knowingly and intentionally cause to any individual and be exempt from the warning requirement pursuant to Health and Safety Code section 25249.10".

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DR. SANDY: And the maximum allowable dose levels are as follows. It starts with 0.2 micrograms every day

or 0.3 micrograms one day in every two days, and so forth. I won't read the rest of that slide.

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DR. SANDY: So lead, as Carol mentioned, was listed as causing reproductive toxicity in 1987 pursuant to the Labor Code. The basis for the listing changed in 2013 to the formally required to be labeled or identified mechanism based on requirements of OSHA. That's the Occupational Safety and Health Administration. And OSHA requires warnings of reproductive effects in areas where the OSHA PEL, or permissible exposure limit, is exceeded, on bags of protective clothing or equipment contaminated with lead, and to workers exposed to any level of lead.

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DR. SANDY: OSHA requires that workers exposed to any level of lead be provided with information that chronic overexposure to lead impairs the reproductive systems of both men and women. OSHA goes on to name the following endpoints: For males effects, decreased sex drive, impotence and sterility, altered structure of sperm cells, miscarriage, and stillbirth.

For female effects, miscarriage and stillbirth, decreased fertility, and abnormal menstrual cycles. And for developmental effects, children born of parents with excess lead levels are more likely to have birth defects,

mental retardation, behavioral disorders, or die during the first year of childhood.

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DR. SANDY: On to the requirements of Proposition 65. At the MADL, the exposure will have no observable effect, assuming exposure at 1,000 times the level. Regulatory guidance on deriving a MADL is provided in Health and Safety Code -- or, sorry, California Code of Regulations section 25801 and 25803 as Carol has described.

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DR. SANDY: Now, in developing the proposed amendments to the lead MADL, one starts with the reproductive toxicity endpoints identified by OSHA. And the reproductive toxicity of lead at high exposure levels has long been recognized. For example, in a 2006 review by U.S. EPA, that review noted that a causal relationship for effects of occupational exposures to lead far above those considered acceptable today on male and female reproductive function and developmental effects from in utero exposure occur.

Now, in a more recent review in 2013, U.S. EPA focused on effects seen at lower doses of lead. For example, at lead levels -- blood lead levels below 40 micrograms per deciliter. And EPA found a causal

relationship for effects on male reproductive function at these lower exposures, and a causal relationship for neurodevelopmental effects from postnatal exposure. And it's important to keep in mind here that postnatal developmental effects are not covered by Proposition 65.

EPA went on to say they did not find a causal association for female reproductive function at these lower levels of lead. And the epidemiological evidence for developmental toxicity from in utero exposure was inconsistent with findings from animal studies mixed.

So in identifying a no observable effect level for lead, OEHHA focused on male reproductive toxicity.

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DR. SANDY: The most sensitive animal study of sufficient quality is an inhalation study in cynomolgus macaques. In this study, damage to the testes was seen and to the seminiferous tubules and a NOEL was not reported in the study.

So using the guidance in section 25803, a surrogate NOEL was obtained by dividing the LOEL by 10. And then you take that NOEL and we multiply by the human body weight for a male of 70 kilograms. And then we divide by 1,000 to get a MADL of 6.7 micrograms per day.

Now, there's a problem with that level. The half-life of lead is longer in the human than in macaques,

and daily exposure to humans at 1,000 times the MADL derived from this animal study, that is 6,700 micrograms per day, will result in blood lead levels above 60 micrograms per deciliter. And those are levels at which male reproductive effects occur in humans.

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DR. SANDY: So we turn to the human studies. And in the U.S. EPA review in 2013, they found that blood levels equal to or greater than 25 micrograms per deciliter were associated with male reproductive effects. That the strongest evidence was for effects on sperm and semen, that studies of men in fertility clinics suffer from selection bias and are not generalizable. And with regard to worker studies, EPA noted the importance of addressing the potential for confounding.

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DR. SANDY: So there are three occupational studies reporting adverse effects of lead on sperm that adjusted for factors that affect sperm. These are the cross-sectional studies of Mahmoud et al. 2005, Bonde et al. 2002, and Telisman et al. 2000.

In the study by Mahmoud et al., reduced sperm count and sperm density at levels of 50 micrograms per deciliter were observed. And they calculated a threshold blood level of 44 micrograms per deciliter.

In the study by Bonde et al., reduced sperm density was observed at 31 micrograms of lead per deciliter and they did not have a lower dose group in that study.

In the study of Telisman et al., they observed reduced sperm counts at 25, 35, and 55 micrograms per deciliter with no significant effect on sperm count observed at 15 or 45 micrograms per deciliter. And this Telisman study is the most sensitive study, and it identifies a blood lead level at which sperm effects are not observed of 15 micrograms per deciliter. So we're taking 15 micrograms per deciliter as the NOEL.

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DR. SANDY: Now, OEHHA has a physiologically based pharmacokinetic model that we can use to go from a blood lead level of 15 micrograms per deciliter to come up with lead intake levels. The PBPK model was published in 2013 after extensive public comment and scientific peer review. It was developed to support reconsideration of the lead standard for California workers.

And as I said, it can be used to calculate intakes that will produce specified blood lead levels. The PBPK model was used to determine NOELs. These are exposures resulting in maximal blood lead levels of 15 micrograms per deciliter. And just to remind you, the

MADL is equal to a NOEL divided by 1,000.

So using this model, we came up with the levels here in the pre-regulatory proposal --

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DR. SANDY: -- with 0.2 micrograms of lead every day as the single-day exposure level. And then for intermittent exposures, we have the rest of the numbers here on this slide.

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DR. SANDY: Now, the proposed MADL for lead of 0.2 micrograms per day when exposures are daily is consistent with the public health goal for drinking water, which is protective of children and infants, and well below other public health guidance values developed to be protective of children, infants, and the fetus, as you can see on this slide, with a public health goal of 0.19 micrograms per day; and the U.S. FDA provisional tolerable intake level for chronic exposures to children of six micrograms per day; and the U.S. FDA PTIL for chronic exposures to women of child-bearing age of 25 micrograms per day.

Thank you.

ACTING DIRECTOR ZEISE: Thank you, Martha.

Now, we'll move towards the -- to the public comment and public input session. So I did see some

people coming in after we started. Are there any others that would like to speak, and if so, if you could fill out a blue card?

And again, Jodie Monaghan will be facilitating this discussion. So if you could please give her your card. And what we've done is organized the cards in alphabetical order by last name. So we'll just -- Jodie will begin and that's how we'll take the comments.

So, Jodie, on to you.

MS. MONAGHAN: I knew that. Thank you. Are we on?

There we are.

So are there any other people who wish to speak other than this gentleman here?

Okay. Then our first speaker will be Caroline Cox. And then Patrick -- and I apologize, I'm going to slaughter everyone's last name -- Elie. Caroline, if you'll come up first, and if Patrick you'll be in the on-deck circle.

And just a reminder, Esther will have the signs and you'll get the hook at five minutes.

MS. COX: So, I'm sorry, I just spoke, and am now taking up your time again, but I hope you can bear with me. So I wanted to just briefly explain -- because I did explain our petition, I wanted to explain what Center for

Environmental Health thinks about OEHHA's proposed response.

And I wanted to start by saying that over the years that the work that I do has intersected with the work that OEHHA does. I've been really, really impressed by the way that OEHHA is so careful in how they use science to inform regulatory proposals. And it's always been something that has really stood out for me. And unfortunately, in this case, I think OEHHA has missed the science.

So I think if you spoke to any OB/GYN or most OB/GYNs in America, the concept that a blood lead level of 15 micrograms per deciliter in a pregnant woman has no observable effect on her child would just not pass muster. In fact, the California Department of Public Health recommends that doctors start being concerned at a level one-third that much, five micrograms per deciliter. And there's good scientific evidence from epidemiological studies that even lower blood lead levels result in reduced IQ or things like IQ in children.

And so I think the intent of Prop 65 was to be really health protective. And so if we're setting a safe harbor level that doesn't protect pregnant women and the children that they will have, I don't think we're following the intent of the law.

And I know that Martha Sandy mentioned that EPA said these effects of prenatal exposure on IQ and similar things in young children were inconsistent. I found nothing in the EPA document that said that, and I searched it pretty carefully.

And then the second thing I wanted to say was about the intermittent exposures and having a series of safe harbor levels based on the frequency of exposure. I think, again, OEHHA unfortunately has missed the current science. So what we now know is that not every day is the same, right? And there are windows of vulnerability to toxic chemicals.

And so, in some instances, it may be fine to average intermittent exposures over a period of time, but if one of those days is the particular stage of pregnancy, which granted, I mean, we haven't identified it down to the day. There's a lot of evidence that it's in the third trimester somewhere, but exactly where hasn't been pinpointed yet. We're not -- again, we're not protecting the most vulnerable parts of our population, pregnant women and the children that they are carrying.

So thank you.

ACTING DIRECTOR ZEISE: Thank you, Caroline.

MS. MONAGHAN: And if I could have John Kendrick in the on-deck circle. And before I bring Patrick, I

encourage each of you to state your name, though you're not required, but it would be helpful. And the time, I promise, will not start till after you finish your name.

MR. ELIE: Good morning. My name is Patrick Elie. I'm here on behalf of Outdoor pro Shop, a California family-owned fish and tackle business since 1993, and ASA, the American Sportfishing Association, a national organization of fish and tackling manufacturers and retailers.

Thanks for the opportunity to express our concerns and contribute to the discussion of this important issue. ASA is submitting written comments and has retained Dr. Michael Lakin, a toxicologist, to address the technical issues, and Dr. Rob Southwick to address the economic impacts of policy change with regard to lead MADL adjustments.

I'm here to speak for the many California businesses, essentially small- and medium-sized companies, and to let OEHHA know some of the many ways that the proposed change the MADL of lead will create far-reaching problems for my business and specifically the fish and tackle industry as a whole.

Changing the lead MADL will affect hundreds of existing consent judgments, confused businesses, disrupt commerce, and create more opportunities for bounty hunter

litigation.

ASA members have been complying with Proposition 65 based on consent judgments since at least 2002. These consent judgments, including some with the Office of Attorney General, are all based on the 0.5 microgram MADL. The consent judgments literally cover all products, not just lead sinkers, because lead is found at a detectable level in just about everything.

The reason that we use consent judgments as a guidepost for compliance is because Proposition 65 regulations are impossible for businesses to understand, let alone apply in the real world. Unlike every other law, there is absolutely no content standard that can be used. Consent judgments have a singular advantage of sending out a bright-line compliance method, which at least can be understood by the average person and easily followed. If OEHHA sets a new MADL, how will the consent judgments be affected.

My company and the members of the ASA organization conduct business as retailers, importers, and manufacturers of goods for the fish and tackle industry. As a retailer, we rely on the manufacturers to comply with California Prop 65. Suppliers are being asked to know which products need to be labeled, and also to be knowledgeable of all the regulations in our State.

It has been a long road to educate our suppliers both domestically and internationally. Changes to this relationship could temporarily or permanently disrupt the supply of goods to be sold in California. We have to ask ourselves, do we just start over, label everything sold in California or both?

As a product developer, our contracts with manufacturers span the globe. This regulation, if adopted, will cause all of these contracts to be reevaluated. This is a costly and difficult task, since the 0.5 MADL has been effect for over 25 years, and all the consent judgments rely on that standard. Mistakes will happen no matter how diligent we may be.

Asking us to start the process over will have a terrible consequence for all the retailers and manufacturers of fishing tackle. Another issue that will be challenging is the question of what do we do with the products we have in inventory that contain no warnings, because they were not required under the current MADL, the existing consent judgments, and other established regulations.

OEHHA needs to make provisions for the millions of products on California shelves that will be affected if these changes go into effect.

Any downward adjustment of the lead MADL will be

an invitation to be so-called -- an invitation to the so-called private enforcer community to sue, not just large manufacturers, but also retailers and small businesses like me.

As you know, these plaintiffs can simply -- sorry, I don't know if that's me -- can simply sue if they allege that a detectable level of lead exposure occurs. The bar is very low and profits very high. These cases are exceedingly complex and costly to defend, so everyone pays.

In this case, where ASA members have already paid their blackmail once and gotten a consent judgment, this change is just an opportunity to put the industry through the lawsuit process again. Because so many industries and companies are going to be affected, OEHHA must do something to prevent open season on businesses, as soon as these new regulations go into effect.

In closing, I and the many ASA members would like to stress four inclusions to be considered if there are changes to the lead MADL.

One, any change in the MADL must be based on unassailable silence; two, evaluate the practical impact of changing Proposition 65 regulations; three, OEHHA and the Attorney General should determine which consent judgments and safe-use determinations will be affected;

and, four, we should take steps to ensure private enforcers cannot sue retailers and distributors for products in their inventories on the effective date that comply with old MADL and regulations.

Please review all the written comments prepared by ASA, Dr. Lakin and Dr. Southwick. Thank you for your time.

MS. MONAGHAN: Mike Lakin is on deck.

MR. KENDRICK: Good morning. My name is John Kendrick. I'm an attorney with the law firm, Lock Lord. I'm appearing on behalf of the nonprofit trade association Independent Cosmetic Manufacturers and Distributors, ICMAD for short.

ICMAD focuses on helping creative and innovative cosmetic companies succeed. Its membership is primarily composed of small entrepreneurial and emerging growth companies in the cosmetics and personal care industries, many of whom are located in California.

Through education representation, the organization promotes product safety, supports scientific efforts in the industry, and advances small businesses that innovate and provide jobs, including jobs for Californians.

After reviewing the Center for Environmental

Health's petition for rule-making, ICMAD has a significant concern with the request to repeal the maximum allowable dose level for lead. The process for determining whether a product is required to carry a warning label is, in many instances, prohibitively expensive for small businesses. Even when a company performs such analysis, they face the threat of bounty hunter litigation, and the additional costs attendant to defending those cases.

OEHHA's developed safe harbor levels serve an important function by guiding businesses and determining whether a warning is necessary. A product with an exposure level below the safe harbor does not need to carry a warning. For chemicals that are listed as causing birth defects or other reproductive harm, the safe harbor is expressed as the MADL.

An established MADL benefits both consumers and producers. Consumers have the benefit of knowing the concrete number at which a warning is required. Producers, such as ICMAD's members, rely on warnings to ensure that appropriate warnings are given to consumers, avoid prohibitive expense of self-certifying a safe level, and have certainty they will not be exposed to unwarranted litigation.

Eliminating the MADL for lead, leaves both consumers and ICMAD's members in a worse position.

Consumers are actually less informed and will likely end up paying more for products or have fewer product choices because of the uncertainty associated with self-certification, and the cost of later defending the self-certification.

Producers will be left with a choice of either putting a warning label on products that don't need a warning label, which misinforms consumers as to risks, or spending money on needless and repetitive self-certification.

ICMAD therefore urges OEHHA not to eliminate the MADL for lead. ICMAD is in the process of reviewing the pre-regulatory draft rule-making language. While it appreciates that the proposed language preserves a MADL, it is reviewing the science that supports an amended MADL with a value of 0.2 micrograms per day, rather than the existing standard.

ICMAD notes that the source of lead in cosmetic products is primarily from natural sources and has been well studied by the U.S. FDA and the EPA. ICMAD plans to submit written comments on the pre-regulatory draft rule-making and hopes to be involved in this process as it moves forward. Thank you for your time.

MS. MONAGHAN: Our next speaker has slides. So if you want to bring the slides up. And Alan Olson is in

the on-deck circle.

Can you pull the slide up?

I think you have to hit the button that shows it.

(Thereupon an overhead presentation was presented as follows.)

DR. LAKIN: Does this run the slides from here?

DR. SANDY: It does.

DR. LAKIN: My name is Mike Lakin. And I'm here -- it's a pleasure to come to you this conference and speak to you all about the lead MADL. We're going to be offering written comments as well as the oral comments, but since it's so abbreviated today, we had to be selective about what we'd say.

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DR. LAKIN: The first thing we're curious about is the status of the process here. At one point, it's indicated that we should come and offer comments on the process. At another point in the notice, it indicated that the decision had already been made. So we're hopeful that the decision is still up for discussion.

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DR. LAKIN: The first thing we're going to talk about is the petition. And the petition basically raises a number of questions that we'd like to look at.

One of these questions is this process that is

currently in use consistent with the regulations.

MS. MONAGHAN: You need to get closer to the mic.

DR. LAKIN: Is the process consistent with the regulations? And we believe that it is inconsistent with the regulations. And certainly in the Statement of Reasons, the drafters of the regulations indicated specifically that this calculation for the MADL was consistent with the purpose of the Act.

Now, a number of technical concerns were raised in the petition about the adequacy of the MADLs. The MADLs are associated with a blood lead level and a air concentration. And that relationship was only established by OEHHA according to the draft comments.

The daily exposure to lead is calculated quite simply and it's about 500 micrograms per day, which is equivalent to the MADL -- the NOEL. And the MADL then is 0.001 of that or half a microgram per day. Since the argument is that the 40 micrograms per deciliter is greater than MADL -- or the no effect levels, that that's not an appropriate number for an MADL.

Now, in developing this number, OSHA considered two PBPK models, one was developed by Rabinowitz and the other was developed by Bernard. The Bernard model was ultimately adopted for calculating the blood lead levels, because it reacted and responded correctly to long-term

exposures. The Rabinowitz model did not.

If you stop exposure after long-term exposures, the blood lead level drops off much more slowly than it does after short-term exposure.

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DR. LAKIN: The Bernard model was developed using the ICRP standard man format, sort of a standard model for doing this type of work. And there a number of assumptions they had to incorporate. One was that the particulate size was one quarter less than one micron, three quarters greater than one micron for any unit of a particulate inhaled.

What that implies is that a certain percentage of the smaller micron size is inhaled. And they assume only 37 percent of that is absorbed into the lungs. The remainder three quarters of the particulate is greater than one micron. That's not -- it does not go into the lungs. It's impacting the back of the throat, the mucociliary action brings it up into the GI tract where it's swallowed. Of that swallowed amount, only eight percent is absorbed. So if you inhale 500 micrograms a day, you end up ingesting -- or absorbing only 76 micrograms.

--o0o--

DR. LAKIN: Woops, went to far.

Now, the way that the model actually calculates the BLL is it takes the output from the model and it adds to that the background baseline level in your blood, which they estimated at the time to be 19 micrograms per deciliter. It also adds a 35 microgram intake amount as the amount that maintains that baseline level.

So they've added two factors on that are not being included in that amount of BLL that is associated with exposure by inhalation to the amount of product you're inhaling.

What this essentially means is that you've got instead of 76 micrograms a day that you're inhaling -- when you inhale 500 that you ingest 76, you're actually ingesting about 111 micrograms, according to the model.

We just sort of layout what the Bernard model says versus the current MADL. It adds 19 micrograms per deciliter to the BLL. It adds 50 percent onto the daily absorbed amount, and then it gives you calculations for different durations of exposure.

So at two years, the exposure would be 2.9, five years, 12, 28 years, 15.

--o0o--

DR. LAKIN: This is the chart that they used to establish these values. As you can see at the first red arrow on the left that the table starts at 19. That's

because that background level has been added in. You can see the second red arrow, the line at 50 shows you for each of those different durations of exposure, starting at two years and going up to 28 years, how much additional material ends up in the blood.

This chart simply shows the concentration of the BLL on the left and time on the bottom.

MS. MONAGHAN: My apologies but your time is up.

DR. LAKIN: I'm done. Thank you.

MS. MONAGHAN: Go ahead finish your sentence and thank you.

DR. LAKIN: Okay. This just shows the short term, that shows long term. Thank you very much.

MS. MONAGHAN: Our next spearer has slides too. And then Anthony Samson is on deck. So you want to wait till your slides come up.

(Thereupon an overhead presentation was presented as follows.)

MR. OLSON: Oh, I can start. It should be at the top, right. SGCD. That one.

Good morning. I'm Alan Olson. I'm here representing the Society of Glass and Ceramic Decorators. It's a global organization. So some of the members decorate mugs, dinnerware, bottles. And certainly you've touched, you know, the products every day.

Can you advance.

DR. SANDY: The little arrow to the left.

--o0o--

MR. OLSON: Okay. I got it.

And actually, I'm going to start on number five because of time. Okay.

So there's probably some background lead in here, because the clay for the substrate, the inorganic pigments that make the decoration come out of the ground. And what we've seen is that in order to get the decoration to stick to the body, you fire it again, if you've done ceramics. So it's really, really hot. It's vitrified. It becomes part of the body.

If you wash it once, you're basically not going to see lead coming off of it. So we've -- you know, our members use a standard leaching test after an initial wash. Basically, the lead is non-detectable. And there could be also lead that comes from packaging, from shipping, and from handling.

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MR. OLSON: And so what we've seen, you know, for the past 26 years since 1989, the worldwide glass and ceramic industry have relied on the current MADL for lead of ½ a microgram per day, based on studies and analyses recognized by the federal government and other entities.

And since 1989, the industry has complied with many, many consent judgments signed in good faith and based on the current MADL of ½ a milligram per -- microgram per day.

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MR. OLSON: So if OEHHA changes the MADL, what are some, you know, unintended consequences?

One is, you know, proposing, you know, exposure every day for 10 years. Maybe from this mug, but probably not from most consumer items. So please, you know, take that into consideration in terms of, again, average Californian exposure. For companies big and small, there might be confusion over how to calculate, you know, an average exposure. And therefore, you've got companies big and small putting warning labels on them.

Further, you know, confusion over, hey, you know, I can comply with the FDA at a half a microgram, but you folks are going to drop the MADL. So I'm going to put a warning label on. I'm going to meet the FDA, but I'm going to be above the MADL, because I've got the warning label on it. So that's an unintended consequence with, you know, no change for the public health, or finally, you can get folks putting, you know, warning labels on and saying I'm not going to pre-wash. You're going to wind up with higher exposures for the public, and not just from

coffee mugs or dinnerware, you know, probably all kinds of other articles.

So please take into consideration.

--o0o--

MR. OLSON: So before you implement changes, you know, again, talk to the other agencies around the country, fully document, you know, how you're going to change the MADL. We have so many consent judgments, you know, you need to talk to the Attorney General here on whether this is going to affect the existing consent judgments. And actually, we'd be willing, you know, to have your write in, run an exposure test, you know, one of the standard ASTM extraction tests, or AOAC that, you know, do represent consumer exposure. Just the presence of lead, you know, somewhere in the body of the mug doesn't mean consumer exposure.

Allow sufficient time for industry to comply for the inventories to work their way out through the supply chain, and bar bounty hunters, you know, from filing 60-day notices until, you know, the inventory works its way through. And, in fact, you know, if there's confusion over exposure in the new MADLs, have the AG look at all the 60-day notices before they go into effect.

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MR. OLSON: So again, you know, look at -- you

know looking carefully, you know, when you're looking at the most sensitive studies. They may have, you know, really low exposure numbers, but take a look to see if they're Klimisch 1 or 2. Take a look at what's in the EU REACH dossiers. That -- you know Klimisch 1 and 2 are good science. So just because it's got a low number doesn't mean that, you know, it's good science.

So thank you. And we'll submit written comments. And if you have any questions, I'll be around for the rest of the day.

Thank you.

MS. MONAGHAN: Can I have Trent Norris up next.

MR. SAMSON: Good morning. My name is Anthony Samson with the California Chamber of Commerce. Thank you OEHHA for having us here today for this very important pre-regulatory workshop.

I'm not a scientist. I don't pretend to understand the science underlying the proposal, so my comments here today are going to focus solely on the policy implications.

And spoken in layman's terms, OEHHA is proposing to reduce the lead threshold by 60 percent for those exposures that cannot be shown to occur less frequently than one day.

Now, acknowledging the Beechnut ruling and the

scientific consensus, OEHHA would permit higher levels when there are intervening days of no exposure. However, OEHHA would also set these levels 60 percent lower than permitted by the Beechnut court.

Again, focusing solely on policy implications, slashing the lead MADL by the amount proposed would mean that many businesses that had previously determined that no warning is required will now have to provide a warning. Many will choose to warn, as they do today, solely to protect themselves from litigation, which will, in turn, exacerbate this overwarning problem on the heels of the Governor's calls for reform in 2013 to do just the opposite.

Further, this cut will substantially increase the amount of businesses vulnerable to litigation, again undermining the Governor's recent calls for reform.

In the context of a law that requires warnings at 0.001 of the no observable effect level, this reduction is particularly harsh and unjustified, and the overall public health justification is questionable.

But putting the policy issues aside, as Trent Norris will discuss after me, and as the Chamber's forthcoming letter will demonstrate, we have concerns and questions about the scientific basis for the proposed MADL as well.

And finally, it is concerning that the MATLAB files for the Leggett plus model were released just yesterday at our request one day before this workshop. Given the late release of these highly technical documents that provide the basis for this proposal, we think an extension of time to submit comments on this proposal is not only warranted, but essential, and I'd be more than happy to submit a formal request for extension. But the time needed now to digest those MATLAB files, it's going to make more time than we thought.

Moving on to the barring averaging for the other MADLs. OEHHA is now redefining other MADLs to be single-day limits only, and is now presenting -- preventing companies from demonstrating on a case-by-case basis, as it was done in the Beechnut case for lead, that it may be appropriate in certain circumstances to average exposures over more than a single day in measuring exposures against the MADL.

And again, I want to be clear that the position is not that averaging is always appropriate, it's that it may be appropriate in certain circumstances.

OEHHA should not, as a policy matter and can't as a scientific matter, conclude categorically that the MADLs are appropriate only for a single-day exposure. This is particularly the case when the MADLs were developed on the

basis of studies with exposure periods longer than a single day, weeks, and month.

Although OEHHA has always expressed its safe harbor levels in the units of quote micrograms a day, this is simply a standard convention, and OEHHA has never officially stated before this pre-regulatory proposal that one day is the appropriate averaging period for all reproductive toxicants and nor would such a statement be scientifically valid.

As with the proposed MADL, this policy will result in a proliferation of new warnings and will make new businesses vulnerable to litigation, again contrary to the Governor's calls for reform in May 2013.

Thank you.

MS. MONAGHAN: David Roe is on deck. Is there anyone else who would like to fill out a blue speaker card and speak today?

MR. NORRIS: Hi. I'm Trent Norris of Arnold and Porter representing the California Chamber of Commerce, and several dozen trade associations that are part of a coalition organized by the Chamber. I'm also not a scientist. I'm an attorney. But it's very important, of course, for consideration of this proposal that everyone understand the science that underlies it.

And so we have a number of questions concerning

the science. We just received the MATLAB files yesterday. These are the inputs to the Leggett model and the outputs of the Leggett model, and we need them in order to evaluate them, and need much more than two weeks in order to be able to do that.

But we have some observations about this. One of them is there was a problem with Leggett plus model that was identified in 2014 after it was released concerning mass balance. That question has not been answered yet, whether the model has been adjusted to reflect those observations.

OEHHA, in running the Leggett plus model, assumed a 10-year exposure period. There's nothing in the documents that describes why 10 years, what's the basis for that? Many consumer products, of course, are used for a period much shorter than 10 years. OEHHA also selected the Telisman study, where -- in which the individuals were employed for at least two years, and there were no effects to sperm at a blood lead level of 15 micrograms per deciliter of blood.

There also was a result that said no effect at 45 micrograms per deciliter of blood. And there's no explanation of this provided in the record or in the study.

This was also a chronic exposure study. And so

we're wondering what's OEHHA's basis for concluding that 15 micrograms per deciliter blood lead level would be the appropriate NOEL for a short time frame of exposure, such as less than two weeks. And, for example, there's a study Sokol study in 1990 - S-o-k-o-l - which found that there was no effect for exposures of less than two weeks.

Responding a bit to some of the CEH petition, which we find very misguided, a few points on that. First, there are only certain endpoints that are relevant under Prop 65. And OEHHA recognizes that. CEH also needs to. And those are the only ones that should be considered here.

Second, the memo quoted in CEH's petition -- PowerPoint presentation from an OEHHA staff person in 1991 was expressly discounted by the court that tried the Beechnut case, and that holding was upheld on appeal as well. This was not OEHHA's official position. And if it was, OEHHA had ample opportunity in a 25-year period to express it as their official position. We find it a very troubling thing that OEHHA would now be using the verb "clarify" their position on this after 25 years of silence on the topic.

And indeed, we think that their silence on that topic is scientifically appropriate, that defendants in Prop 65 cases should have the ability to present evidence

showing what the appropriate averaging period is for a given chemical exposure, and should not be limited to a single day exposure

There's really no justification for restricting the type of evidence that a court could see on these issues, and for saying, oh, it must be a single-day exposure. If there's some concern about this being health protective, I would remind everyone that Prop 65 from the statute has a one thousand fold uncertainty factor, meaning you first determine the level at which there is no effect, and then you divide that level by 1,000 in order to set the level at which someone deserves a warning under Proposition 65. So there's already plenty of deference given to safety factors.

CEH also refers to a 15 microgram per deciliter blood lead level, which, as creating effects for instance, or maybe a five deciliter -- five microgram per deciliter level as creating effects under the public health goals, again there's 1,000-fold safety factor here.

The -- OSHA used an eight percent absorption factor, which Mr. Lakin demonstrated. We believe OEHHA is using 15 percent here, and we're not quite sure why that's justified as well.

And then finally, I would just note the macaque study, the monkey study, that Dr. Sandy mentioned earlier,

there's been no effort to adjust the numbers in that for the half-life differences in humans versus macaques, which may give us a number that more closely represents the actual number.

And then finally, the whole idea of not being able to average exposures over time for other safe harbor MADLs is completely not germane or responsive in any way to the CEH petition. We don't understand why it's been incorporated into this or why it's part of this same hearing today, because the CEH petition addressed only the lead MADL.

Thank you.

ACTING DIRECTOR ZEISE: Thank you. Before David itself makes his comments, I just want to clarify one thing, and that's that the pharmacokinetic model did in fact take into account the issue of mass balance that was brought up. So the current model has addressed that issue.

And then the MATLAB approach has been posted for some time. What we did recently get was a request for us to post the code associated with the calculation at 15 micrograms per deciliter as a -- and to post something where anyone could back-calculate what the exposure level was, but the actual code itself has been posted for a number -- actually for, I think, a couple years now, since

we developed the model for use by Cal/OSHA.

MR. NORRIS: Can I explain and clarify?

My understanding is that the Leggett model is akin to a spreadsheet in which there are formulas. And yes, that has been posted for -- since 2014, I believe, but that what we did not have, until yesterday, was what were the inputs to those formulas and the exact outputs of those formulas. And that was necessary to just understand what are the assumptions that are going into OEHHA's calculation that results in the 0.2 up to eight microgram per day chart.

MR. ROE: Are there any questions on things?

My name is David Roe, and I represent the California Association of Bow Tie Wearers.

(Laughter.)

MR. ROE: And since this is a pre-regulatory hearing, my comments will be equally informal.

First, although, of course, one of the first things you ever hear in a situation like this is we need more time, more delay, OEHHA needs to be aware that you are under something of a clock, because the Mateel litigation has not been stayed pending this rule-making or pre-rule-making, and, at some point, that judge is likely to be impatient if delay is too long. That's just a fact of legal life in this context.

I don't want to make any statements today or offer any opinions about the legality of the proposal, meaning whether or not it comports with the language of Prop 65 and furthers its purposes. I think practically speaking what everyone is searching for is the modern equivalent of what we had for a very long time with the 0.5 microgram per day exposure for any single day, which was an uneasy consensus.

For various reasons everybody sat still for that for a quarter century. And what, in fact, you're looking for today is a modern version of the same uneasy consensus. And I say that again independent of any opinion about what's legal and what's not legal.

One thing for sure that ought to emerge from whatever OEHHA does is it should be more protective of human health than 0.5 on any single day. If it's not, then it's just backsliding. And I don't think that would be acceptable to anybody looking out for the public health in this context.

The obvious key issue, which OEHHA has teed up -- or actually it was teed up by the defendants in the Beechnut case, and then OEHHA has picked up the ball, is the question of averaging. Again, I don't want to offer any opinion, at this point, about scientific basis or not for averaging, but I do think it's worth saying that

whatever averaging is in a regulatory proposal should not go nearly as far out as the 116 days in the current pre-regulatory proposal. That's quite pernicious and leads to the potential for unacceptably large single-day exposures.

Averaging, of course, creates difficulties. It could even be thought of as pernicious on the enforcement side, because, of course, the argument is we tested the product, it has this much lead it, and the counter is, oh no, but people only use it every Christmas.

Whatever the outcome there, there ought to be an extremely strong element in the regulation that whoever argues that exposures have not taken place in the interim bears a very strong burden of proof by clear and convincing evidence to disprove a working assumption that exposure occurs every day.

I was somewhat amused to see the Claude Rains performance of I'm shocked, shocked to learn that you can't average, because, of course, for 25 years all of the settlements that you heard about from other people have all been based on that assumption. Whether or not OEHHA was official, and there's some dispute about that, quite clear that a quarter century of practice is everybody knows it's 0.5 in any single day. So there's no shocking surprise about that.

But when you get to averaging, and, of course, I'm talking about a proposal that contemplates some degree of averaging, the other thing to be well aware of is the precedent value on other reproductive toxins. This says no, but, of curse, the next step will be yes.

The Claude Rains comment applies equally to the Chamber's written position that they're shocked to discover that you can't use the arithmetic mean, they're shocked to discover that you can't average across multiple lots. And suffice it to say, that's contrary to 25 years of experience.

My final comment is to remind OEHHA what it already knows well, but perhaps the room may not be aware, this is a safe harbor proposal. It is entirely optional. It is not a what's the healthy level. It is the level that, if you are a potential defendant, you can for sure be protected by. That is obviously very different from a regulatory level that would be required. It's not something OEHHA has to do, and it is something that, as you do it, you should realize this is a safety valve and be treated as that.

Thank you.

MS. MONAGHAN: Mike Easter.

MR. SOMERS: Hi. My name is Eric Somers. I'm an attorney with the Lexington Law Group. I represent both

CEH, and I'm counsel of record in the Mateel case challenging the existing MADL.

I'm pleased -- one of my comments was that we need the MATLAB data. And I didn't know that came out last night. So thank you for doing that. We had a PRA request in on that.

We're also pleased that OEHHA has now clarified publicly that the existing MADLs are all single day. We think that helps clarify some of the pre- and post-Beechnut confusion, so we're pleased with that.

But as to the proposal, from a practitioner's standpoint -- and I'm not a scientist. I don't play one on TV -- we think frequency, adding that element to the MADL is not a good idea. Bringing the number up to -- from ½ microgram to eight micrograms on 116-day exposure is 16 times the current level. We think that's as bad as the defense side thinks dropping the single day to a 0.2 is.

But we can agree that I don't think adding frequency as a variable in an exposure assessment, it's going to add complexity. It's going to add cost. It's going to create more litigation. So I think just as a concept it's not a great idea.

Prop 65 is very complicated in that it doesn't specify concentration in a product. It expresses, and we

like this, an exposure to a person. It focuses on the person. But adding frequency into the exposure assessment adds a level of complexity to that that's going to create more litigation, more cost, more arguments.

The other reason I don't think it's a good idea is I think the data on frequency is poor. The NHANES data is based on surveys of what people remember they ate and how frequently. I can't remember what I ate last week for lunch on Tuesday. And I suspect, while my memory is not great, I don't think the average American's memory is that much better as to what they ate over a period of time.

So to take -- even if it's scientifically valid, to add that element into the MADL calculation I think is a mistake. And the final point is it doesn't prohibit a defendant from using frequency data. This is just a MADL. It's a safe harbor as David pointed out, and a defendant can go out and set their own no observable effect level using frequency of consumption as a variable any time they want.

But for the purpose of the MADL is to give businesses that don't have the ability to establish a MADL -- to establish their own exposure assessment to rely on it in a simple way, and it gives plaintiffs a simple way to rely on it. And as David said, it's something we've been doing for 25 years. And adding frequency to

that, what's supposed to be a simple process, I think, is a mistake.

Thank you.

MR. EASTER: Hi. My name is Mike Easter. I work with Dr. Lakin, and I just wanted to finish up on his presentation over here.

Specifically, we're asking OEHHA to identify the defects of the existing MADL, both with respect to the threshold, and the process of converting the exposure to a blood lead level that exceeds this threshold.

With that in mind, to the extent that there's a decision to go forward to come up with another MADL value, that proposed approach needs to identify how it remedies the defects on the existing MADL, both with respect to the threshold and the process by which you convert exposure ostensibly to a blood lead level.

With respect to the information that's put forward as part of the conceptual approach, we applaud the idea of getting away from the one-size-fits-all value, and to look at the unique aspects of lead toxicity and build that into the MADL for lead, specifically route-specific differences with lead, the absorption rates that are different, the amount of exposure, the frequency of exposure, the duration of exposure, and even perhaps the age of exposure, so that whatever MADL value is identified

or range of values, they take into account what the objectives of Prop 65 are.

It's a warning statute. This value is to make the determination when to warn and not to warn. It's not designed to be a health protective statute, where we apply the precautionary principle. It's designed to identify under what conditions we need to warn to avoid underwarning and overwarning, consistent with Governor Brown's proposals to reform Proposition 65.

Let's see. And again, we look forward to having the opportunity to work with OEHHA, and appreciate getting the MATLAB data out on the web so there's more transparency, and that way all of the stakeholders can have informed input to reach an optimal approach for looking at MADLs for this compound and possibly using this as a template for other compounds.

Thank you.

MS. MONAGHAN: Is there anyone else who wishes to speak this morning?

Okay. Then I'd like to turn it back to you for next steps and closing remarks.

ACTING DIRECTOR ZEISE: Great. Well, I'd like to really thank everyone for their comments. You've given us a lot to think about, in terms of practicality, in terms of context, in terms of the analysis. We're really

looking forward to hearing your -- to reading your written comments that may go into a bit more detail on what you've already teed up. So very much looking forward to that.

We do have an October 28th deadline. We're limited in terms of our ability to extend that, because of ongoing litigation. Carol, I don't know if you have anything to add in that regard.

CHIEF COUNSEL MONAHAN-CUMMINGS: Well, since it came up through a couple of commenters, OEHHA is in the process of defending a lawsuit that was filed by Mateel Environmental Justice something. I can't remember the name of it. No offense to the folks that run Mateel.

But in any event, we're defending that case, and that -- and they have challenged the existing MADL, the basis for that as being illegal from the time it was adopted. And so we are in the situation where we need to proceed with the rule-making on this particular MADL in a timely way, more so than maybe looking at some of the other pre-regulatory proposals that we'll be talking about this afternoon and on Monday.

So I think that the request for additional time is probably not going to be -- we can't really accommodate that, but we do remind everyone that this is a pre-regulatory proposal. And when we get to the point of making a formal regulatory proposal, then there will be

the usual 45-day comment period for the public to comment on the formal proposal, and any additional changes end up in comment periods as well. So there will be additional opportunities to comment.

ACTING DIRECTOR ZEISE: Thanks, Carol. So as Carol said, the next step is to take into account the comments and to come up with a regulatory proposal that will follow the standard APA process, for which there will be hearing and ample time for comment, but we really are looking forward to receiving your written comments that do lay out in more detail what you've presented.

And so I'd like to thank again the audience for their participation and people on the web. We do have on the screen where you can send your written comments to Monet Vela. That's -- if you could submit them by 5:00 p.m. on October 28th. We have the address here, and we do prefer electronic submissions. It just makes everything a lot easier for us, but we also can receive hard copy.

Carol, is there something else?

Okay. And so we really do hope -- we're going to look at the comments very carefully. And the plan is to get our regulatory proposal out by the end of this year.

So I'd like to thank again -- thank you all again, and thank our staff for all the hard work putting this workshop together. And thank Jodie for her excellent

facilitation of the workshop.

(Thereupon the California OEHHA workshop adjourned at 11:35 p.m.)

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
License No. 10063