# PRE-REGULATORY WORKSHOP

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

POTENTIAL AMENDMENTS TO

TITLE 27, CCR SECTION 25821

STATE OF CALIFORNIA

ELIHU HARRIS BUILDING

AUDITORIUM

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OAKLAND, CALIFORNIA

MONDAY, OCTOBER 19, 2015 10:03 A.M.

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

## APPEARANCES

## STAFF:

Mr. Allan Hirsch, Chief Deputy Director

Dr. Melanie Marty, Acting Deputy Director

Ms. Carol Monahan-Cummings, Chief Counsel

#### FACILITATOR:

Mr. Jeff Loux, UC Davis

# ALSO PRESENT:

Ms. Caroline Cox, Center for Environmental Health

Mr. Mike Easter, EnSIGHT

Mr. Trent Norris, California Chamber of Commerce

Mr. Gary Roberts, Dentons

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#### PROCEEDINGS

CHIEF DEPUTY DIRECTOR HIRSCH: We're on the record. Good morning. My name is Allan Hirsch. I'm Chief Deputy Director for the Office of Environmental Health Hazard Assessment. I'd like to thank you for starting your work week off with us and attending our workshop on the Proposition 65 pre-regulatory proposal concerning -- am I too loud?

CHIEF COUNSEL MONAHAN-CUMMINGS: Yeah, you're too close.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay -- concerning the calculation of the reasonably anticipated level of intake or exposure to listed chemicals in consumer products. So with me up here is Dr. Melanie Marty, who is our Acting Deputy Director for Scientific Affairs and Carol Monahan-Cummings our Chief Counsel. Also, with us is Jeff Loux of UC Davis extension. He will be facilitating today's workshop. And he will explain his role in greater detail in a few minutes.

So as many of you know, this is the third in a series of four public meetings over a six-day period, in which we've been taking input on four pre-regulatory proposals that are officially separate, but are intended, at least in concept, to work together as a package. And the first two of these meetings took place last Wednesday

in Sacramento, where we discussed a proposal for updating the maximum allowable dose level for lead, as well as a proposal identifying naturally occurring levels of lead and arsenic in certain foods.

At 1:00 p.m. this afternoon in the same auditorium, we will have a workshop on a proposal covering how one could calculate concentrations of listed chemicals in products. But this morning, we'll be discussing a pre-regulatory proposal for how one should calculate the level of exposure that consumers would incur to listed chemicals, and specifically reproductive toxicants in consumer products.

This concept consists of adding one sentence to section 25821 of our Proposition 65 regs, which would specify that the calculations should utilize the arithmetic mean of the rate of intake or exposure for users of that product.

And to start that discussion, we'll first hear the legal background on this proposal from Carol Monahan-Cummings, followed by an overview of the proposal itself by Dr. Melanie Marty.

But first, I just wanted to remind you that this workshop actually is not being webcast, as this building does not have that capability. Unfortunately, we were not able to find a room with webcasting capabilities in the

time frame that we needed, but we do have the next best thing, which is that an audio recording of this workshop is being made and it will be transcribed and a transcript of this workshop will be available in the very near future.

So we know that there are strongly held opinions as to how exposures to chemicals in products should be calculated, and we look forward to hearing these thoughts from you both today and in written comments that are submitted during the written comment period, which runs through November 17th.

So with that, I'd like to turn over the microphone to our facilitator Jeff Loux of UC Davis Extension, who will go over process details.

MR. LOUX: Thanks, Allan. And thanks for everyone being here. Just some quick housekeeping details to make sure that we kind of stay on time and stay focused. Emergency exits, there are four of them around the room. As you came into one, one here, two in the back. The restrooms, if you need them, are a little bit hard to find. Just go out and go down to the right, and you actually have to go through a little construction. There's a little going on, but just keep going and persevere and you'll get there. They are open and ready.

on time and make sure that we get through the workshop and get through the issues and basically that -- have a neutral at UC Davis Extension's Collaboration Center is assisting OEHHA in that regard.

I put up on this little flip chart just a couple of basic sort of meeting management rules. I think we're a pretty small group. We probably don't need to worry about them, but if we kind of just stick to those agreements, recognizing that we will have some strong differences of opinion, and that's a good thing. That's what these kind of pre-workshops are all about, and if we can respect that and respect the time.

I've only got a couple of speaker cards, so I suspect time is not going to be an issue at all. I have two. If anyone does wish to speak, what you want to do is fill out one of these blue cards. And we have them up front or I can pass them out and then give them to me and then I'll kind of go through the speakers.

We shouldn't have any problem with time as a result of that, because we don't have a lot of speakers yet. But if we do, Monet is here with the big sign that says, you know, five minutes, three minutes, that sort of thing just to keep us on time, but I don't think that's going to be a problem today at all.

I'd say we do have the court recorder, which will

then turn into official court reporting, so all of this is being recorded but not webcasted, as Allan said. I think that's all the logistics and housekeeping that we need.

Okay. So I'll turn it over to Carol and then Melanie.

CHIEF COUNSEL MONAHAN-CUMMINGS: I'm going to go to the next slide and you can see which is better.

MR. LOUX: Do we want to go lights down or is this good?

CHIEF COUNSEL MONAHAN-CUMMINGS: So what's your preference, do you want to leave the lights up? Can you see well enough?

MR. LOUX: That's pretty good.

CHIEF COUNSEL MONAHAN-CUMMINGS: Okay. I'll just leave it that way. I'd hate to have you all go to sleep this early in the morning.

Good morning. I'm Carol Monahan-Cummings, Chief Counsel for OEHHA. And I just want to give a couple little background comments on the reason that we're here for this workshop. It's a little bit different than the ones that we had last week. Particularly the one in the morning last week was responding to a petition for rule-making. We don't have any requests -- formal requests for rule-making on the subjects that we're here on today. However, as a lot of you know there

were -- there's been some court decisions, in particular one in ELF versus Beechnut case that interpreted OEHHA's regulations.

And what happens in court cases is that you have experts that are hired by each side in the litigation.

And their objective in the litigation is to win. And so there's -- the paid experts will give their opinions and then the court has to rely on those opinions, look at the relevant law and come to a conclusion.

So when we looked at the decision in the ELF versus Beechnut case, we felt that the court incorrectly interpreted a couple of our regulations, and that the decision is contrary to the intent of our regulations.

So we've determined that we want to clarify a couple of issues in our existing regulations, which are actually pretty old. They were adopted nearly 30 years ago, but they've served -- they've served well, and they're -- for the most part, they still represent the position of OEHHA. But there are certain terms within the regulations that we think need to be defined more clearly.

And one of those we're going to talk about this morning that has to do with what an average user of a product might look like. We want to remind you that the law -- this particular law does not ban the use of chemicals. It doesn't limit the amount of a chemical that

can be in a product. What it does is it requires a warning for individuals who are exposed to a chemical that the State has determined causes cancer or reproductive effects.

And so the purpose of the law is to provide warnings to individuals that are exposed. And so it's important that it -- the terminology in the statute talking about exposure in individual and other terms in the statute be well defined in the regulations.

So what we're talking about today, as Allan mentioned, is what an average user of a product might be. And so we're going to -- I'm going to have Melanie explain to you the change that we are proposing for the regulation, at least as a pre-regulatory concept. I want to encourage you to give us your ideas on the concept. That's what we -- why we do pre-regulatory workshops, so that we can hear from the public before we take a formal regulatory action. And we're encouraging you to put your comments in writing, as well as make them orally, because it can be kind of a complicated question.

Okay. And I don't think I had anything else I wanted to add at this point, but I'm happy to answer questions later, if you'd like.

DR. MARTY: Good morning I'm Melanie Marty. I'm Acting Deputy Director for the Science Division at OEHHA.

So Prop 65 requires businesses, as you know, to provide a warning to consumers when the level of exposure from a consumer product exceeds a specific amount of a listed chemical. The level of exposure to a listed chemical is determined by multiplying the quote level in question to the concentration -- you can think about it as the concentration of chemical in a given medium times the reasonably anticipated rate of exposure for an individual to a given medium.

For exposures to consumer products, a level of exposure is calculated using the reasonably anticipated rate or intake of exposure for average users of the product.

We're talking about a possible amendment today to the regulation. So Prop 65 and existing implementing regulations are not specific about how intake or exposure of an average consumer is determined. This lack of clarity can lead to incorrect determinations that some product related exposures are exempt from Prop 65 warnings.

This possible regulatory action would amend section 25821(c)(2) to clarify that the reasonably anticipated rate of intake or exposure to a listed chemical is to be calculated as the arithmetic mean of intake or exposure for product users. This will help

businesses to correctly determine the rate of intake or exposure and decide whether a warning is required.

Intakes or exposures vary for users of products and can be represented by a range of values. So this is schematically shown at the bottom of this slide. The range can be characterized as a distribution from lowest to highest exposure. It could be a bell shaped curve, which is what you see on the left of the slide, even on each side, or it could be skewed a little bit. In this case, we're showing a right skewed distribution on the right hand side of this slide.

The distribution of food intakes is most often skewed to the right, meaning that a relatively smaller number of people consume the product at significantly higher amounts than other consumers of the product.

Now, why would we use the arithmetic mean to determine the average? So the existing regulation right now is not clear whether average should be characterized by the arithmetic mean or the geometric mean or some people like to use a median. The geometric mean, in essence, underweights the rate of exposure of those people whose consumption is nearer to the higher end of the range. The median does not address consumption near the high end of the range at all. It just says half the values are below this and half the values are above this.

The arithmetic mean weights all the values for intake rate equally and does not discount exposures near to the high end of the range. The geometric mean will produce a lower average consumption rate than the higher -- than the arithmetic mean in this case.

The geometric mean is commonly used for a rating system that scores products based on two or more criteria, which may cause the range of data values sometimes to span multiple orders of magnitude.

The arithmetic mean is commonly used for averaging a single criteria, in this case, daily consumption, measured with a single metric.

This slides gives us an example of the difference between the geometric mean and the arithmetic mean for a set of numbers. The geometric mean is essentially the nth root of the product of n numbers. So, in this case, assume it's five milligrams per day intake of something, 10, 25, and 30. If you do the geometric mean of that, you end up with 13.9. The arithmetic mean is what we're all familiar with. It's the sum of n numbers divided by n. In this case, the arithmetic mean is 17.5.

The possible amendment that we're proposing is reasonably anticipated rate of intake or exposure to a listed chemical is calculated as the arithmetic mean of the rate of intake or exposure for users of the product.

MR. LOUX: Thanks, Carol and Melanie.

So we're kind of moving now into the question portion and the public comment portion. And I think we'll be fine time-wise. It should be good. Does anyone else need a speaker card, if you didn't pick one up, if you intend to speak now that you've heard the presentation. I still only have two, so those are the two I'll call out.

If you need a speaker card after you kind of heard things?

And does anyone have a speaker card out there in the audience that I didn't -- I've got Trent Norris and Caroline Cox.

Okay. Any other speakers?

Well, we'll have no problem accommodating however we want to do it. So the idea is the speakers kind of come on up here and kind of talk into that microphone. That will help our recorder make sure. So why don't we have Trent Norris come up first. And this is, you know, questions to Allan, or Melanie, or Carol and also comments and discussion.

MR. NORRIS: Thanks. Hi. I'm Trent Norris of Arnold and Porter here on behalf of the California Chamber of Commerce and a large coalition of trade associations organized by the chamber. Anthony Samson of the Chamber sends his regrets. He had a conflict he could not move

today, but he asked me to present our oral comments. And, of course, we'll be presenting written comments prior to the deadline.

The Chamber believes strongly that OEHHA should not take a one-size-fits-all approach by requiring that the reasonably anticipated rate of exposure or intake be based solely on the arithmetic mean of the distribution of exposure rates. Nothing in the statute requires OEHHA to take this outlier position. And this has not been OEHHA's expressed position in the past. So we strongly object to any implication that this is merely a clarification of OEHHA's long-standing position. This issue comes up in case after case under Proposition 65. There have been thousands of them over the 30 years or so that this has been in effect. And OEHHA has never weighed in on this issue in any formal manner.

I personally am unaware of OEHHA ever taking this position, even informally, in 22 years of practice and meetings with staff of a OEHHA, as well as staff of the Attorney General's office.

Any estimate of the average term is only as good as the data and methods that are used for the estimate. Statisticians know this. They also know there are different ways to calculate the average, the geometric mean, the arithmetic mean, and the median are examples of

that. Government agencies also know this.

The U.S. Centers for Disease Control and Prevention, which is responsible for the database on food consumption that is referenced in the Prop 65 regulations specifically, has guidance addressing when to use the geometric and arithmetic means. And they say, and I quote, "In instances where the data are highly skewed, geometric means should be used". A geometric mean, unlike the arithmetic mean, minimizes the effect of very high or low values, which could bias the mean if a straight average, i.e. arithmetic mean, were calculated. U.S. EPA calls for the geometric mean when dealing with skewed data distributions for exposure assessments as well. And OEHHA itself has used the geometric mean.

As one example, OEHHA determined the cancer potency for phenylhydrazine hydrochloride as the geometric mean of potencies derived for each of the data sets analyzed.

So the determination of average, the determine used in the regulations, therefore must be made based on analysis of the distribution. Is it highly skewed? Is it a bell curve? Where does it fit?

The California Attorney General has recognized this in briefings in multiple cases seeking to determine, and the term they use is, the central tendency of a

distribution to be the average - that's the term used in the regulations - which can, in fact, be something other than the arithmetic mean.

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It would also be bad policy for OEHHA to move in this direction. For skewed distributions, such as OEHHA acknowledges is true for most foods, using the arithmetic mean would require warnings for many more consumers than are actually necessary. In many cases, the arithmetic mean of exposure is at the 80th or 85th percentile of the entire distribution, as compared to the geometric mean, which is closer to the median, at the 55th or 60th percentile.

A warning on a consumer product is provided to all users. So the practical effect of this proposal would be to change the law, so that we are now providing warnings for all users of the product, where only 15 to 20 percent of the users are exposed above the threshold level, in other words, those above the 80th or 85th percentile.

This runs directly contrary to the Governor's reform initiative to make warnings under Prop 65 more meaningful for consumers and to have fewer warnings as well.

This also is obviously a reaction to the Beechnut decision, since it only addresses reproductive toxicants

and not carcinogens. There's nothing in the statement that addresses why that would be the case.

And furthermore, it is contrary to the facts to say that you're averaging only one particular criterion here. In food cases, there indeed are three criteria at least that get averaged together in order the figure out the actual exposure, one is the amount consumed per eating occasion, two is the eating occasions per day, i.e. the frequency of consumption, how frequently people consume the product, and the third is the concentration of the chemical.

When those three are multiplied together, the distribution becomes more skewed. So because this is talking about the rate of intake or exposure to the chemical, you have to look at all three of those criteria. That gives you a skewed distribution, in many cases for foods, and for perhaps for in other products. And it's therefore appropriate, as OEHHA recognizes, when there's more than one criteria involved to use the geometric mean.

I should also point out that this affects not only the warning provision of Prop 65, but the discharge prohibition. So one cannot say, well, it's just all about warnings. Prop 65 bans the discharge of chemicals to a source of drinking water, or to land where it may enter a source of drinking water, above the particular level set

for that chemical. And exposure, under this regulation, would be calculated in exact three same way. The exemption would apply the same, and so you could indeed be banning products as a result of this.

So in sum, we believe strongly that OEHHA should not adopt this proposed language, should leave it to the courts discretion after reviewing the science, reviewing the specific distribution for the chemical at issue and for the product at issue, to determine what average means, and to thereby implement the regulations, as we believe they were intended, almost 30 years ago.

Thank you.

MR. LOUX: Thanks, Trent.

The next speaker I have is Caroline Cox. And does anybody else think they may want to speak, but they don't have a blue card and want the fill one out. And are there any other blue cards out there, now that you've gotten going and you will want to speak in

MS. COX: Good morning. My name is Caroline Cox. And I'm from the Center for Environmental Health here in Oakland. I just want to speak briefly in support of this proposal. You know, I was thinking about those voters back in 1986 who made Proposition 65 into a law. And I doubt any of them were thinking about the meaning of the word average. But I'm sure if you had asked any of those

voters what they thought average meant, they would have thought it meant the plain old, ordinary, what we call arithmetic mean. The kind of average that we all learned to do in fourth grade, right?

And I also think there was a strong presumption on the voters who supported the law that they wanted to be protected. The reason that they voted for Proposition 65 was they wanted more protection from toxic chemicals. And I think OEHHA has made it really clear in the materials that they prepared for this meeting that the more health protective way to define average is as the arithmetic mean.

So we're in support of the proposal.

I would request that, if possible, OEHHA clarify -- and if I'm the only one who doesn't understand this, I ask your forgiveness. But under what specific circumstances does this definition of average apply? As Trent mentioned, with food cases, there's typically an issue about how much you eat, what your serving size or consumption amount is, and then there's also an issue of how often you eat it or frequency of consumption.

And it wasn't clear to me whether this was meant to apply to both those things or one or the other. So if there's a way to clarify that, I think that would be very useful.

Thank you.

MR. LOUX: Thank you, Caroline.

Okay. The next speaker I have is Gary Roberts.

And I ask again, is there anyone else that has a card who wants to speak, card out there, or who needs a card, needs one and wants to speak and didn't get a chance to sign up?

Okay. Gary.

MR. ROBERTS: Thank you. Good morning. I'm Gary Roberts of Dentons. I have a few questions and a comment.

And my questions are, is this a science based action or a policy action, number one?

Number two, why is there a rush?

Number three, there is a statement on page three of the pre-regulatory comments that is kind of -- I read as a fact statement. It's two sentences and I'll read it now for those who don't have the three page comments with them.

Quote, "The geometric mean could be acceptable for a rating system that scores products based on two or more criteria, such as price, availability, and sales data. However, the geometric mean is not the appropriate metric for identifying average consumption levels of a food or a consumer product", closed quote. What is the citation for that statement?

And then my comment is that this action is

remarkably unjustified in light of the thousand-fold safety factor present in the statute.

Thank you.

MR. LOUX: Thank you, Gary.

The next speaker I have is Mike Easter? And again, is there anyone else who has a speaker card? It would be good for us to get a sense of -- rather than just having them come in one at a time, because then we won't quite know how much time to give them. Does anyone else need a speaker card? Need a blank one?

MR. EASTER: My name is Mike Easter. I'm a toxicologist and a principal at EnSIGHT. I do a lot of Proposition 65 risk assessments. And when I saw this, I was concerned that, from what I can -- from what I understand is a policy decision, not premised upon any scientific determination.

If we keep in mind that, as Trent pointed out, that this is a warning statute, and this information that we're talking about today is used to make the determination when a warning is necessary, we want to keep it towards the center where the average user is for the reasons he cite, specifically to avoid underwarning and overwarning.

In the context of looking at the variables that go into an exposure assessment, there's a number of them.

Some of them may be distributed log normally, some may be arithmetic, harmonically, there's a whole -- there's a myriad or indefinite.

And it just seems to me that when we go through and make the determination as to whether a warning is required, we want to apply objective scientific process.

So kind of getting back to this proposed rule, it seems inappropriate to make the determination a priori that all distributions are best described by an arithmetic mean. I think really what would be appropriate here is a process to make the determination of how the treat the data.

And rather than having a proposed regulation addressing it, maybe other types of guidance information might be useful in that regard. I know that you guys prepare interpretive guidance for a number of other aspects of these exposure assessments. And this might be a better fit, rather than a priori rule that it could result in overwarning or underwarning.

Thank you.

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MR. LOUX: Thanks, Mike.

Is there anyone else who wants to speak or ask a question or address?

Anybody else?

No. So Allan, Melanie, Carol, do you guys want

to respond to any of these? There were a few direct questions. There were a couple of comments, a couple of suggestions. Do you want to respond to any of them or -- it's up to you.

DR. MARTY: In terms of the question that Gary Roberts asked, is this a science based or policy based?

So I looked at it from a science perspective,

but, you know, obviously there's choices. And so you could say it's maybe a mix.

And then somebody made a statement that OEHHA has used the geometric mean and gave an example of one of the slope factors, cancer potency factors. And, yes, we have done that. We've done that where you have a number of data sets that you can analyze, and they might be very -- from very different types of experiments. So they really aren't the same way of measuring something. So, yes, we have done that.

Now, in terms of using average versus -- or arithmetic versus geometric versus any percentile in an exposure assessment, in OEHHA's other risk assessment programs, we typically use an arithmetic mean for a skewed distribution, plus one of the high end percentiles to characterize exposures to a population.

Anyone else want to respond to it? Allan, Carol, anything?

No. Okay. Anybody else out in audience? One more shot at it, since we've got plenty of time. Anybody else want to ask a question?

Okay. All right.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Well, I'd like to thank everyone for making the effort to come here this morning and participate in our workshop. I think rather than try to respond off the top of our heads to comments that we've heard, we'll definitely go back and think about them. And we assume that we'll see those same comments perhaps expounded upon in your written comments.

Hold on, I think Dr. Marty has something else to say.

DR. MARTY: I just wanted to add in the other programs where we're looking at the arithmetic mean of skewed distributions. Those are in peer reviewed scientifically peer reviewed risk assessment guidelines.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. So again, we'll be thinking about these comments as well as written comments that need to be submitted to us by the end of the comment period on November 17th.

So again, we would encourage those comments to be emailed to Monet Vela of our staff, at Monet, M-o-n-e-t dot V-i-l-l-a at OEHHA.ca.gov.

CHIEF COUNSEL MONAHAN-CUMMINGS: V-e-l-a,

1 | V-e-l-a.

CHIEF DEPUTY DIRECTOR HIRSCH: Oh. Okay. Your right. My a apologies.

4 MR. LOUX: It's on the agenda notice and on the 5 website.

CHIEF DEPUTY DIRECTOR HIRSCH: I can't believe I did that.

(Laughter.)

DR. MARTY: You must have been thinking of that famous actress Monet Villa.

(Laughter.)

DR. MARTY: It was a joke. Sorry.

CHIEF DEPUTY DIRECTOR HIRSCH: I was writing it out yesterday and had taken the day off.

Can you also snail mail comments to Monet

Vela -- and I see it in my notes here I have that right,

V-e-l-a, at the Office of Environmental Health Hazard

Assessment, 1001 I Street, Sacramento, 95812. And of

course details including proper spellings are available on

our website at oehha.ca.gov.

So again the next step is for us to -- is to review both oral and written comments and then presumably to produce both an official proposed regulation and an Initial Statement of Reasons. And we would then expect to initiate the State's official regulatory process

of -- which would include a public hearing and comment period on the official proposed reg.

This workshop is really just an early preliminary step in that regulatory process. So thanks again to the staff and to the Jeff Loux for helping us today. And I'm sure we'll see many of you back here at 1:00 o'clock for the afternoon workshop on measuring concentrations of listed chemicals in products.

(Thereupon the workshop concluded at 10:37 AM.)

# CERTIFICATE OF REPORTER

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

That I am a disinterested person herein; that the foregoing California Office of Environmental Health Hazard Assessment workshop was recorded electronically and transcribed under my direction, by computer-assisted transcription in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California.

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

IN WITNESS WHEREOF, I have hereunto set my hand this 27th day of October, 2015.

James & Titte

JAMES F. PETERS, CSR, RPR
Certified Shorthand Reporter
License No. 10063