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

1515 CLAY STREET

OAKLAND, CALIFORNIA

MONDAY, OCTOBER 19, 2015

1:03 P.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. Melanie Marty, Acting Deputy Director, Scientific Affairs

Ms. Carol Monahan-Cummings, Chief Counsel

FACILITATOR:

Mr. Jeff Loux, UC Davis

ALSO PRESENT:

Dr. Mike Lakin, EnSIGHT

Mr. Trent Norris, California Chamber of Commerce

Mr. Gary Roberts, Dentons

Ms. Emily Rooney, Agricultural Council of California

I N D E X

	PAGE
Opening remarks by Acting Director Zeise	1
Remarks by Mr. Loux	3
Presentation by Chief Counsel Monahan-Cummings	4
Presentation by Dr. Marty	7
Ms. Rooney	10
Mr. Norris	12
Dr. Lakin	17
Mr. Roberts	18
Closing remarks by Acting Director Zeise	21
Adjournment	21
Reporter's Certificate	22

P R O C E E D I N G S

MR. LOUX: We are on the record.

ACTING DIRECTOR ZEISE: I'd like to welcome everyone. I'm Lauren Zeise I'm Acting Director for the Office of Environmental Health Hazard Assessment, or OEHHA. I'd like to welcome everyone in the audience. We don't have this meeting being webcast, because the facilities for webcasting aren't available at this facility, but there will be a transcript. The meeting is being transcribed and a transcript will be made available.

So I'd like to introduce staff who is up -- who is with me at the table. We've got Dr. Melanie Marty, who's Acting Deputy Director for Scientific Affairs, Carol Monahan-Cummings, who's our chief legal counsel -- or chief counsel.

This afternoon, we're discussing our pre-regulatory concept on an approach for determining concentrations of listed reproductive toxicants in food products. So this is food products as sold to the consumer. This is the last of four events covering pre-regulatory concepts that we're providing to clarify regulations.

Last Wednesday in Sacramento, we heard comments on our pre-regulatory concept for revising the MADL for lead and other pre-regulatory concept for adding a new

section to our naturally occurring regulations that would provide safe harbor concentrations to chemicals in -- listed chemicals in food. And the new section would start with looking at lead in fresh produce and meats and arsenic in rice.

And this morning we had a workshop on the pre-regulatory concept for further clarifying what is meant by exposure to the average consumer.

So today, this afternoon, we're addressing the issue of averaging concentrations of a chemical in a given food product. Food products of the same type can vary depending on production line, sources of the produce or meats that go into the food, and various other factors.

Under this pre-regulatory concept, concentrations of listed reproductive toxicants in food products marketed to the consumer could not be averaged if they come from different lots. So to start the discussion on this pre-regulatory concept, we'll hear about the legal setting from Carol Monahan-Cummings and then we'll be hearing our pre-reg concept and background on it from Dr. Melanie Marty. And we've asked Jeff Loux from UC Davis to facilitate this workshop for us. And he'll start by covering some process details before we turn to Carol Monahan.

Jeff.

MR. LOUX: I think I need batteries.

ACTING DIRECTOR ZEISE: Maybe you have to move down three feet

(Laughter.)

MR. LOUX: I'll go over here. Thanks, Lauren.

Yeah, just quickly, I think many of you, almost all of you, I think were here this morning, but a few weren't. So just quick housekeeping. The emergency exits are all around us, all four corners. The bathroom just outside down to the right. You've got to go through some construction traffic, so kind of keep moving down that way.

The agenda, Lauren pretty much covered it, but after we have the technical review and legal discussion, that will be the time for public comment and for all the questions. So if you could hold your questions kind of till the end, that seemed to work out pretty well.

If you want to speak, we want you to fill out one of these cards, so we can sort of keep track of you. I've only got a couple of them so far. Does anyone else need a card or have a card to turn in at this point?

Okay. I don't think we'll have any time problem, because we only have a few speakers. So we won't have a time problem, but just be respectful of time. We have some little meeting agreements over there. I think you

guys saw them this morning. They're just a good way to kind of keep everybody on track and keep us all being professional and courteous and all that sort of thing. So hopefully, we don't need to worry too much about that.

And we are -- we do have a court recorder, I guess you might say, that will then be transcribed verbatim. So that will be available in the absence of the webcast.

So I think with that, Carol, I think I'll turn it over to you for the legal side.

And if you need one of these, just shout out or put a hand up and we'll get you one.

CHIEF COUNSEL MONAHAN-CUMMINGS: Good afternoon. So I think everybody -- is there anybody here that wasn't here this morning?

Oh, okay. All right. I've got to start over. All right.

(Laughter.)

CHIEF COUNSEL MONAHAN-CUMMINGS: So I just want to give you a little bit of background in terms of where we are right now and how we got here. As you know, our regulations, most of them, were adopted nearly 30 years ago under Prop 65. And they've served the State well in terms of setting out the structure for listing chemicals and determining safe harbor levels, but in recent years

there's been some questions that have come up fairly frequently in court cases. And a good example of that is one that we were talking about today, it has to do with the -- how one goes about determining the concentration of a chemical in a food product. What -- this morning there were some questions that kind of got to -- or asked -- pointed out the issue that there -- that Prop 65, as you all know, is a mix of law, science, and policy. And this is an example of the decision that will be based on law, science, and policy.

So we're -- today, we're asking for your input on our proposal for looking at when it's appropriate to use composite averaging of samples of chemicals in food products. So, to some extent, we agreed with the decision in the Beechnut case -- Environmental Law Foundation versus Beechnut. We agreed that there are situations, particularly with foods, where you need to do some sampling to come up with what an average exposure might be. But we thought that the decision went too far in allowing the companies to average over time and space as well as within the individual lots of a particular product.

So there was also a question about why we needed to be involved at this point. And in answer to that question, the Beechnut decision is final, and it's being

used in various forums to -- because it's good law. And so we feel like rather than have these kinds of questions decided in the courts based on expert testimony, that there should be an open public process for developing the regulation and interpreting it, and rather than the more expensive case by case determination. And so that's one of the reasons that we're here with this proposal.

So from our perspective, we believe that there's been -- since there's not as clear guidance as there could have been in the regulation, there -- this has led to an incorrect conclusion that sometimes the -- that the existing regulation would allow averaging of the measured concentration of a listed chemical in the food product across lots, manufactured in different states and countries, and over extended periods of time.

So we recognize that chemical concentrations can vary from lot to lot. And for most reproductive toxicants exposure is to be evaluated for consumption on the date the food was actually eaten. If the concentration of a listed chemical is high in one lot and low in other, allowing the concentrations to be averaged over multiple lots could allow food related exposures to a listed chemical to occur without the required warning for reproductive toxicity, even where they -- the exposures may be quite high from an individual product.

So that's really kind of the context that we're in right now in terms of feeling that we need to provide some guidance in how we interpret our regulations. And so I'm going to turn the discussion over the Melanie Marty and she can explain the proposal in more detail.

DR. MARTY: Thanks, Carol. I'm Melanie Marty, Acting Director for the Scientific Affairs Division.

Section 25821 basically says for purposes of the Act, the level in question means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible and does not include exposure to a listed chemical from any other source or product.

So the problem that we see, the Prop 65 statute and the regulations don't specify procedures for determining the level in question. This has allowed people to come to the incorrect conclusion that it's okay to average measured concentrations of a listed chemical in food products across lots manufactured from different places and at different times.

And as Carol just mentioned, averaging a high level of a listed chemical in one lot with low levels in other lots could allow food related exposure that exceeds a maximum allowable dose level without a required warning.

So a possible amendment to section 25821. The chemical concentration in a food product is based on a single lot of the final product in the form it will be purchased by the consumer. And the rationale for this is the typical consumer's exposure to a listed reproductive toxicant would be by consumption, of a final product from a single batch or lot.

Another possible amendment to section 25821, a lot is that quantity of a food product offered for consumer purchase having uniform characteristics and quality that is generated by one producer during a single production run on a single processing line. The lot numbers are already used to trace foods. We're all familiar with recalls where they say lot number X, Y, or Z. And we do recognize the specific lot definitions depend on the type of food.

So the intent is that food manufacturers could use their existing quality control procedures to address their responsibilities related to Prop 65. And we'd like to provide guidance for food manufacturers who wish to test their products. Note that this does not require product testing.

We looked at a number of sources of definitions of a lot, U.S. Food and Drug Administration, California Department of Public Health, and the European Commission.

Another possible amendment to section 25821, chemical concentrations may not be averaged across lots. So the rationale then is Prop 65 is intended to provide warnings for exposures of individuals to listed chemicals by a specific product or locations. Then averaging the concentration again across lots could allow food related exposures that exceed the MADL without a required warning. So this is obviously inconsistent with the intent of the Act.

More language. Concentrations of listed chemical in the lot should be determined using a representative sample or other scientifically valid methodology for ensuring the concentration calculated accurately reflects the average concentration of the listed chemical in the lot.

So we understand that variation within a lot will occur of a listed chemical, but it's expected to be a lot less than between lots. Testing each individual food item is obviously completely impractical to characterize exposure. So FDA has established sampling methods that may be appropriate for this kind of composite sampling. And then the composite samples themselves could be appropriate to characterize the average concentration in the lot.

Back to Jeff.

MR. LOUX: Does anyone else need a card or have a card?

Okay. All right so we'll just kind of start in and then we can get some dialogue or discussion going as we need to.

The first one I have is Emily -- Emily Rooney. So come on up to this lovely podium and -- and the next one I have is Trent. And that's actually all I've got is just the two. So if other want to weigh in, go ahead and fill out a card while we're waiting and we'll add you in.

MS. ROONEY: Good afternoon. My name is Emily Rooney. I'm president of Agricultural Council of California. Ag Council represents approximately 15,000 farmers across the State of California from small farmer owned businesses to some of the world's best known brands. A handful of our membership has been actively engaged in this issue and some of them have not had to participate at this point.

But everybody is sort of trying to digest all the proposed regulations and trying to understand collectively what they mean for our industry.

First, I want to thank OEHHA for creating a procedure that actually fits within our quality assurance testing programs. So as many of you know, we have a lot of quantity of food moving through processing plants at a

very rapid rate. And so trying to find something that works in our existing processing procedures is immensely helpful.

Prior to reviewing this pre-regulatory discussion draft, or quite frankly even seeing it, I went out to our membership and I asked what does a lot mean to them? And I got a very wide variety of responses. And based on my interpretation of this draft language, I think it would potentially benefit one of my 35 members who does not have a Prop 65 -- a known Prop 65 issues on their hands at this point. Most of it comes down to the language.

While the language in the regulatory draft does say you want testing of a final product, the way OEHHA defines lot is coming from a single producer on a single processing line is problematic. That's sort of the hang-up piece for our folks.

The only way I can figure out how to get that testing done would be to do it -- to test the product in its fresh form that's prior to processing, if you truly want a single grower and, understanding the single source of that product. And due to the perishability of a lot of agricultural products that may or may not be workable.

We are going to be submitting written comments, so I don't have a solution for you right now.

(Laughter.)

MS. ROONEY: But we'll be trying to work through that and offering up some recommendations in our written comments. But thank you very much for your time and thanks for trying to work within our scope of work. So thank you.

MR. LOUX: Thanks, Emily.

Okay. The next one it's Trent. And anyone else? Are there anyone else -- do you have a blue deal?

Okay. Why don't I get you one while Trent is talking.

MR. NORRIS: Good afternoon. Trent Norris of Arnold and Porter. I'm here on behalf of the California Chamber of Commerce and its coalition of trade associations and other interested parties. Anthony Samson of the Chamber had an unavoidable conflict today and so I'm providing the Chamber's comments. And of course we will be providing written comments prior to the deadline.

The Chamber believes that OEHHA's proposal here is another one-size-fits-all approach to evaluating when warnings are required and that it will also lead to over warning, just as the arithmetic mean proposal that we discussed this morning would. We think it's unworkable from both the practical standpoint and a cost standpoint.

Nothing in the law requires that in determining a level in question, you have to look just at a lot of -- an

individual lot of a product. To evaluate this reasonably anticipated rate of exposure by average users, testing needs to account for typical concentration levels, and -- in order to replicate what consumers actually experience. And that is not necessarily on a lot by lot basis.

We think that this should be left to a case by case determination by courts in enforcements actions, just as it occurred in the Beechnut case and in many cases that came before Beechnut as well.

The concept of single lot testing raises a number of practical problems. And we think OEHHA has a misunderstanding of how agricultural production of food processing actually works in reality. There is no standard definition of what a lot means. And, in fact, references to lot numbers don't work for many in the industry, particularly where you have continuous production. So that products may be time stamped but you have a 24/7 production line, such that there's no start and stop to any individual lot. And it's not the way people think about it, it's not the way even food safety regulators think about it.

Many products are not produced as discrete lots. When commodities, for instance, are supplied to a cannery, they may come from different growers and different regions on their way into the processing plant. And a lot number

assigned on a can of spinach for instance doesn't tell you that all of the spinach in that lot came from the same grower or the same harvest or the same farm.

The same is true, of course, for more processed foods like baked goods, cereals, chips, almost every type of food you can think of. The inputs are mixed in all sorts of ways before they arrive at the factory.

Ultimately, we think this proposal will lead to overwarning. It would, indeed, make companies test each and every lot to reduce the risk of litigation. And the reason is Prop 65's unique burden of proof, which is reversed. So in Prop 65 litigation, if a plaintiff were to produce a test result for -- again, let me take a can of spinach as an example. If they produce a test result on one can of spinach showing that it's high in lead for instance, and above the level that they think requires a warning, the producer, under this proposal of that can of spinach, will not be able to rebut that result without actually having tested that lot in order to say, no, you've got a can within the lot that was particularly high in lead, but the lot on whole on the average meets Prop 65's requirements.

So this will require testing of every single lot. Companies may prefer to warn, instead of testing each and every lot. And indeed, because testing is expensive, and

it takes time, that may be the most rational responses to this proposal, if indeed it is enacted.

There's very limited time with respect to perishable commodities, of course. And by the time test results come back, the canned produce may be on the shelves. There is not a way to determine, as cans are processing and passing the line very rapidly, the amount of any given Prop 65 listed chemical that may be present in that can on an instantaneous basis.

And as a result, you'll find companies needing to perhaps, I don't know, hold the cans, and then sticker those that are above a level before they get shipped out. That's very labor intensive and time intensive.

We believe that OEHHA should not adopt this proposed language because courts are fullly capable of evaluating testing data and variability across a distribution of numbers, in order to determine whether sampling is representative, has this been appropriately characterized, and whether averaging is appropriate across lots, or, in the rare case, just within lots, for instance, or perhaps even on a smaller basis than a lot-by-lot basis.

This is a common issue that courts deal with in all sorts of situations, in environmental cases, in consumer class actions, in evaluating survey data, civil

rights cases where there's a broad range of possible ways to evaluate it and figure out what's typical here, what's average, what's representative.

And we particularly object to the implication that averaging across an entire amount of product that's in the market at any given time is inconsistent with the intent of the Act -- that it's inconsistent with the intent of the Act to allow averaging across lots, because it would allow exposures to individuals that exceed the MADL, for instance.

But that is true of any averaging that you do, whether it's within a lot or across lots. Even within a lot, you would have higher numbers and lower numbers. And so some individual who eats the can of spinach that has more lead in it than other cans in the lot might be entitled to a warning under this sort of interpretation of the law. That would obviously be impractical.

So the question is where to draw the lines and courts do this all the time and quite effectively. We also think there's no factual basis for the idea that there's more variability across lots than within lots. If there were the same degree of variability, then there would be no need for lot-by-lot averaging, and you could characterize the entire scope of things just by looking at everything broadly.

Those are the kind of fact-by-fact determinations -- case-by-case determinations that we think courts are very well equipped to handle.

This issue of lot-by-lot averaging was a make-believe issue in the Beechnut case at the trial level. And it only became the excuse of the claims counsel in that case to try to reverse the trial court. They were grasping at straws and they failed in that effort, but they did not point out a fundamental flaw in Proposition 65 or in the current OEHHA regulations, which indeed serve people very well.

There's no systematic problem here that needs to be created -- corrected. And OEHHA's proposal attempts to correct what we think is a non-existent problem.

So again, we think the most practical response that food producers would have to this proposal would be to provide warnings. And that would be completely inconsistent with the Governor's call for both fewer and more meaningful warnings.

Thank you.

MR. LOUX: Okay the next speaker is Mike Lakin. Anyone else need a card or have a card? Is anyone else going to add in?

DR. LAKIN: My name is Mike Lakin. It's a pleasure to be here today. I just want to make a couple

of comments on some of the technical concerns we have about the proposal.

Right now, we're thinking about reproductive and developmental toxicants as having relatively short windows of susceptibility, and therefore single lots often have adequate data to describe the exposure to those products.

However, there are other products that may have larger windows of susceptibility, running instead of days, maybe weeks, months, or even longer. Some of the male toxicants, for instance, are likely to have longer exposure durations. In those instances, it might be necessary and essential to be able to average between lots to be able to understand did exposure pattern that occurs over longer periods of time.

Secondly, some of the appropriateness of averaging over time probably should not be mandated up front. It's probably something that should be decided on an individual basis. In some cases, when you look at these exposure durations, and exposures for different patterns of reproductive toxicants, it's not a one-size-fits all. So if you say an absolute rule that you cannot average, or average across lots is not allowed, you may end up finding yourself in a situation that prevents you from doing proper work. So just a caution to think broadly when you put these rules up, because I think

there's some exceptions to the rule that might be critical.

Thank you.

MR. LOUX: Okay. Anyone else? Anyone else want to speak?

Okay. Gary Roberts?

Anybody else? Others who need a blue card or have a blue card?

Okay. Next.

MR. ROBERTS: I have questions. Based on what you've described, why is this concept not applicable to the proof element of exposure?

Number two, has OEHHA undertaken any feasibility study for this regulation, and if not, does it intend to before moving forward?

Number three, which courts have had difficulty with this? I heard reference to the Beechnut court, but the only Beechnut decision I read did not address the substance of the issues. So it would be helpful for me to know which courts have difficulty with this issue.

And I have a comment. Given the thousand-fold safety factor in the proposition, I do not consider this undertaking warranted.

MR. LOUX: Okay. Anybody else? Any other speakers? Other questions? Dialogue, discussion,

anything?

Okay. It's back to you guys. Lauren, Melanie, Carol, do you guys want to respond. We've got three questions from Gary. We've got a couple others.

ACTING DIRECTOR ZEISE: I do just have a follow-up question to Gary's question. You said why is this not -- something about being applicable to a proof element. So I was a little confused by that question.

MR. ROBERTS: Underpinning your proposal, as I read it, is the notion that evidence from one lot should not be extrapolated to another lot. If that is true, that should apply to the plaintiff's burden of establishing exposure. Have you considered that is the question?

ACTING DIRECTOR ZEISE: I think you've given us some questions to think about and which we will, and appreciate your coming forward and posing these. Thank you.

MR. LOUX: Okay. Any other responses or anything you guys want to hand back in?

Is there anybody else out there? I just kind of want to make sure people kind of wait and then they decide later?

No. Okay. This is a workshop, so --

DR. MARTY: I just wanted to thank people for coming and use the written comments to provide

alternatives. So Emily in the back of room. It sounded like you had some ideas, because that will be really helpful.

MR. LOUX: Okay.

ACTING DIRECTOR ZEISE: So, yes, thank you all for coming and we really do look forward to your comments, and hope that as you come up with some suggestions, you give enough detail for us to kind of think pretty carefully about it.

And of course, you can submit your comments to Monet Vela at Monet.Vela@OEHHA.ca.gov. And I believe the final due date is November 17th for comments.

So our next step is going to be to take these comments into account, consider them very carefully. Hopefully, we'll have additional suggestions for how we get at this issue, and to come up with a regulatory proposal. And, of course, our regulatory proposals follow the Administrative Procedures Act, which involve hearing, public comment, and so forth.

So thanks again to everyone for coming to our meeting. Carol or Melanie, further issues?

Okay. And thank you so much, Jeff, for facilitating. And to staff for all the work in putting the meeting together. Thank you.

(Thereupon the workshop concluded at 1:34 PM.)

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

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, 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 24th day of October, 2015.

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