

PRE-REGULATORY WORKSHOP
STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
POTENTIAL AMENDMENTS TO
TITLE 27, CCR SECTION 25821

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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

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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

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

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

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

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

25 Jeff.

1 MR. LOUX: I think I need batteries.

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

4 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

18 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Back to Jeff.

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

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

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

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

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

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

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

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

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

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

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

25 (Laughter.)

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

6 MR. LOUX: Thanks, Emily.

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

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

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

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

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

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

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

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

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

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

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

8 Ultimately, we think this proposal will lead to
9 overwarning. It would, indeed, make companies test each
10 and every lot to reduce the risk of litigation. And the
11 reason is Prop 65's unique burden of proof, which is
12 reversed. So in Prop 65 litigation, if a plaintiff were
13 to produce a test result for -- again, let me take a can
14 of spinach as an example. If they produce a test result
15 on one can of spinach showing that it's high in lead for
16 instance, and above the level that they think requires a
17 warning, the producer, under this proposal of that can of
18 spinach, will not be able to rebut that result without
19 actually having tested that lot in order to say, no,
20 you've got a can within the lot that was particularly high
21 in lead, but the lot on whole on the average meets Prop
22 65's requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 Thank you.

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

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

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

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

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

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

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

3 Thank you.

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

6 Okay. Gary Roberts?

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

9 Okay. Next.

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

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

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

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

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

1 anything?

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

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

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

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

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

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

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

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

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

4 MR. LOUX: Okay.

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

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

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

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

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

25 (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