PUBLIC HEARING

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

In the matter of:

Notice of Proposed Rulemaking,

Title 27, California Code of
Regulations, Proposed Adoption of
New Section Under Article 7, No
Significant Risk Levels Section
25704 Exposures to Listed Chemicals
in Coffee Posing No Significant Risk)

CALEPA HEADQUARTERS

SIERRA HEARING ROOM

1001 I STREET

SACRAMENTO, CALIFORNIA

THURSDAY, AUGUST 16, 2018 10:00 A.M.

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

APPEARANCES

STAFF:

- Dr. Lauren Zeise, Director
- Mr. Allan Hirsch, Chief Deputy Director
- Ms. Carol Monahan Cummings, Chief Counsel
- Mr. Carl DeNigris, Senior Counsel
- Ms. Martha Sandy, Chief, Reproductive and Cancer Hazard Assessment Branch

ALSO PRESENT:

- Mr. Robert Donohue, Canteen
- Mr. John Hornung
- Ms. Sandra Larson, NAMA, CAVC
- Dr. Alan Leviton, National Coffee Association
- Mr. Jeffrey Margulies, California Retailers Association
- Mr. Raphael Metzger, Council for Education and Research on Toxics
- Mr. William Murray, National Coffee Association
- Mr. Trent Norris, National Coffee Association
- Mr. Adam Regele, California Chamber of Commerce

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PROCEEDINGS

DIRECTOR ZEISE: Okay. If everyone would like to take their seats, we can get started.

Good morning. I'm Lauren Zeise. I'm Director of the Office of Environmental Health Hazard Assessment or OEHHA. I'd like to welcome you here to our hearing on the proposed regulation of Proposition 65 listed chemicals in coffee. We're really looking forward to hearing your comments. And I'd also like to welcome, in addition to people in the room, people that are listening via webcast. So with that, I'd like to introduce the OEHHA staff members at the table.

First, Al -- Oh, we're not on yet. The clock is wrong.

We'll take a step back and start in two minutes.

All right. Once again, I'd just like to welcome

everyone in the room and attending via webcast to our Proposition 65 hearing on chemicals -- listed Proposition 65 chemicals in coffee.

So welcome everyone in the room and on the webcast. We're looking forward to hearing everyone's comments. And with that, I'd like to introduce the OEHHA staff people at the table. Allan Hirsch will be our hearing officer. He's OEHHA's Chief Deputy Director.

Next to him is Carol Monahan Cummings, the OEHHA Chief

Counsel. On the other side of Allan is Dr. Martha Sandy.

She's Chief of the Reproductive and Cancer Hazard

Assessment Branch. And then at the end of the table is

Carl DeNigris, who's our OEHHA staff attorney.

And with that, I'll turn the meeting over to Allan Hirsch.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thank you very much, Dr. Zeise.

So -- yeah, so we have a few housekeeping items to go through at the beginning of our hearing here. Just if you need to use the restrooms during the hearing, you would go out the door in back of you, turn left, go down the corridor, make another left, and the bathrooms are on your right. So that's two lefts and one right.

In the unlikely event that there is an emergency during this hearing, the most direct way out of the building is to go out of the doors in back of you, then go down the stairs toward the right and head right out of the building. We tend to have fire drills here in the spring. So given that it's mid-August, we should be okay.

And then lastly, again, as you probably -- as you know, this is being webcast. I'd like to thank all the people watching on the webcast for taking time out of your day to join us remotely.

And if you -- for those of you in the room who

wanted to text a colleague that it is on the webcast, they can access it by going to video.CalEPA - that's C-a-l-e-p-a -- .ca.gov.

So under the provisions of the Administrative Procedure Act, this is the time and place set for the presentation of comments, orally or in writing, regarding the proposed rulemaking that exposures to listed chemicals in coffee do not pose a significant cancer risk.

This is regulation proposed for adoption by the Office of Environmental Health Hazard Assessment. OEHHA - that's our name in short - considers this proceeding to be a quasi-legislative hearing, because it is carrying out a rulemaking function delegated to it by statute. OEHHA will take under submission all written comments and oral statements submitted or made during this hearing.

The Director of OEHHA, Dr. Zeise, has designated me to conduct this hearing on her behalf. And I will be doing so in accordance with provisions of the Administrative Procedure Act.

A certified court reporter, on the right side of the room, is here and will be making a transcript of this hearing. The transcript and all exhibits and evidence presented at this hearing will be included in the admin administrative record for this rulemaking. The written public comment period for the proposed rulemaking will

close on August 30th, 2018.

So for organizational purposes, we request that those of you wishing to speak at this hearing complete a blue speaker's card. There should be a pile of them on the table in the back of the room. And you can give it to Monet Vela over on the left-hand side, though you're not required to do so in order to speak.

Also, I want to be sure that you are aware that because this is a formal public hearing, we will essentially be in listening mode. Some you perhaps have been to pre-regulatory workshops or you may have seen some of the scientific panel meeting that we have where there's a lot of back and forth between presenters and people on the dais. This works a little bit differently.

This is a formal public hearing and we basically go by the State procedures in which we're here basically in listening mode. We can ask a clarifying question -- you know, a relatively simple clarifying questions of presenters if we like. Similarly, presenters can ask simple clarifying questions for us if they like. But again, we're basically here in listening mode. So if we don't ask a lot of questions, that doesn't mean that we're not interested or we're not listening to what the presenters are saying.

So with only two exceptions, we're enforcing a

five minute limit for each speaker at this hearing. So if you have a long or complex argument, we strongly encourage you to submit those arguments in writing to us by the August 30th deadline. Submitting lengthy comments in writing ensures that we will take as much time as we need to review them and we'll give them full consideration.

So we did announce several weeks ago that people or groups could send us requests for extended presentations at today's hearing. And we received, and have approved, two requests for extended presentations from the Council for Education and Research on Toxics, and the National Coffee Association.

If we adopt the final regulation concerning listed chemicals in coffee, we will have written responses to comments that we receive at today's hearing, as well as the written comments we receive during the written comment period.

So again, if you have a detailed comment, again we strongly recommend that you submit it to us in writing by the August 30th deadline.

So when you are called, to enable the audience to hear you and to ensure that your comments are recorded for the record, please come to the microphone over there, when you are called to speak. It's helpful to us and for the court reporter if you state your name and the organization

that you represent, if any. However, you're not required to do so in order to speak.

So at this time, I'm going to pass the microphone over to our Chief Counsel, Carol Monahan Cummings.

CHIEF COUNSEL MONAHAN CUMMINGS: Thank you, Allan.

I wanted to mention that on the back of the -back the table, I'm not sure if Allan mentioned it, there
are a few copies of the materials that -- including the
notice, the statement of reasons, and the proposed
regulation, as well as copies of the slides that we're
going to use today. So for anybody that wants to get
those, they're in the back. If we run out, let us know,
and we'll go ahead and make some more copies.

So as it was mentioned before, I'm the Chief Counsel for OEHHA. Our legal office is responsible for developing and shepherding our regulations through the Administrative Procedure Act process.

On this particular regulation, my -- one of my Senior Staff Counsel -- Carl DeNigris is the person that has been working on this regulation primarily. And so I'm going to have him go ahead and give you a brief overview of the basis for the regulation. And then, of course, we'll also have a discussion about the scientific basis of the regulation.

1 So if you could go ahead, Carl.

(Thereupon an overhead presentation was presented as follows.)

SENIOR STAFF COUNSEL DeNIGRIS: Thank you.

In order to save time, I have provided a copy of the text of the proposed regulation, the Initial Statement of Reasons, and the notice of the proposed rulemaking to the court reporter to be marked as Exhibit A to the hearing transcript, and included in the hearing record.

(Exhibit A marked for identification.)

SENIOR STAFF COUNSEL DeNIGRIS: As required by the Administrative Procedure Act, the public and interested parties were notified of this proposed regulation at least 45 days prior to today's hearing. The notice of this proposed regulation was published on OEHHA's website and sent by email to interested groups and individuals on June 15th, 2018, and was published in the California Regulatory Notice Register on June 22nd, 2018.

I'll now briefly go over the legal authority for the proposed regulation starting with some background on Proposition 65.

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SENIOR STAFF COUNSEL DeNIGRIS: Health and Safety Code section 25249.6 generally requires businesses to provide a clear and reasonable warning before exposing a

person in California to a listed chemical.

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Code section 25249.10 subsection (c) provides an exemption to the warning requirement when an exposure to a listed carcinogen poses no significant risk of cancer.

SENIOR STAFF COUNSEL DeNIGRIS: Health and Safety

And as the lead agency for implementation of Proposition 65, OEHHA may adopt regulations establishing levels of exposure that pose no significant risk.

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SENIOR STAFF COUNSEL DeNIGRIS: Which brings us to our proposed regulatory text. OEHHA is proposing to add a new section to Title 27 of the California Code of Regulations section 25704, which would State that exposures to listed chemicals in coffee created by, and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.

So the proposed regulation does not focus on any specific chemical, but rather the complex chemical mixture that is coffee.

I'll now turn the meeting over to Dr. Martha
Sandy to discuss this unique mixture and briefly summarize
the scientific basis for the proposed regulation.

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DR. SANDY: Thank you, Carl.

I'll start with a definition of coffee. In the proposed regulation, coffee refers to a beverage made by percolation, infusion, or decoction from the roasted seeds of a coffee plant.

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DR. SANDY: Coffee is a unique and complex mixture. Coffee contains numerous chemicals formed during the roasting of coffee beans, and the brewing process, including carcinogens that are listed under Proposition 65, as well as other chemicals that are considered to be protective against cancer.

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DR. SANDY: So coffee, as a mixture, has been studied extensively in humans. There has been a recent evaluation of these human cancer studies as well as other relevant information by the International Agency for Research on Cancer. And it's been published in 2018 in the IARC monographs on the evaluation of carcinogenic risks to humans entitled *Drinking Coffee*, *Mate*, and *Very Hot Beverages*. It's volume 116.

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DR. SANDY: And now I'll present IARC's findings on coffee. IARC concluded -- well, and these findings are based on a review of over a thousand studies in humans, animals, in vitro systems, and other experimental systems.

1 | This review evaluated 460 human epidemiologic studies.

2 | And those studies included numerous well-conducted

3 | prospective cohort and population-based case-control

studies. IARC concluded there was inadequate evidence for

5 | the carcinogenicity of drinking coffee, and classified

coffee in Group 3, not classifiable as to its

carcinogenicity to humans.

IARC also found that there is strong evidence in humans that coffee has antioxidant effects.

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DR. SANDY: And now to run through IARC's findings for specific cancers in humans. IARC concluded that drinking coffee reduces the risk of cancers of the liver and the uterine endometrium that moderate -- there's moderate evidence that drinking coffee reduces the risk of co-colorectal adenoma, which is a precursor lesion for most colorectal cancers.

Studies show that drinking coffee either reduces the risk or has no effect on the risk of breast cancer. There is evidence suggesting lack of carcinogenicity for cancers of the pancreas and prostate. And there is inadequate evidence of an association between coffee drinking and other types of cancers.

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DR. SANDY: There are many beneficial compounds

in coffee. These include: Soluble and insoluble fiber that can reduce the uptake of certain carcinogens into the body; chemicals that appear to increase colon motility reducing contact time within the colon; many antioxidants and free radical scavengers; and several anti-inflammatory chemicals.

And in intervention trials where humans are given a time period, usually a week or so, where they do not consume coffee and blood measurements are taken for certain biomarkers of effect. And then they're started on a certain dose of coffee for a certain period of time.

Coffee consumption has been shown to decrease markers of inflammation, to decrease markers of oxidative stress, and to increase antioxidant capacity in humans.

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DR. SANDY: So here's the proposed regulatory text again, which Carl presented. And I'll just emphasize something that's in the Initial Statement of Reasons, that this regulation does not address exposures to listed chemicals in coffee that may occur if the chemicals are intentionally added to the coffee mixture, or enter the mixture as contaminants, through a means other than the inherent processes of roasting coffee beans or brewing coffee.

Thank you.

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CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thank you. So there's an opportunity now if anyone has simple clarifying questions about the regulation or the presentations that you've heard, this is a chance to ask those, not public comments, per se.

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So, okay, seeing none, okay. That's great. We will now begin the public comment part of our public hearing. So as I said earlier, we had authorized extended presentations for two groups, Council for Research and Education on Toxics[SIC]. And we authorized a presentation of 30 to 45 minutes for that, and followed by speakers from the National Coffee Association, which is 20 to 30 minutes.

So I think I'd like to ask the representative of CERT, Mr. Metzger to make his presentation.

(Thereupon an overhead presentation was presented as follows.)

MR. METZGER: Good morning. It's a pleasure being here.

My name is Raphael Metzger. I am the general counsel of the Council for Education and Research on Toxics, and I will be speaking in opposition to this proposed regulation.

Do we have a clicker?

CHIEF DEPUTY DIRECTOR HIRSCH: Are you able to

hear Mr. Metzger? Is -- I just -- you sounded a little bit lower on the volume. So I just wanted to make sure you're audible.

MR. METZGER: Is that better?
Okay.

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MR. METZGER: What do I do with this?

Well, as you can see, the first slide has one word on it, acrylamide. Although this is a hearing about coffee, it's actually, in my client's view, a hearing about acrylamide. And I'll talk about my client and its interest in this after we address acrylamide, because they tie in.

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MR. METZGER: So acrylamide is a carcinogen.

It's been on the Prop 65 list, oh, I think, since the early nineties. And it's classified as a carcinogen by all the relevant agencies, IARC, NTP, EPA, OEHHA and Heath Council of Netherlands, which says it should be regarded as carcinogenic to humans. All of the agencies are in agreement that it is a carcinogen. We don't have a glyphosate issue here.

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MR. METZGER: And the basis of IARC's classification was sufficient evidence in supportive

evidence of genotoxicity, acrylamide and glycidamide that's its reactive metabolite - induce hemoglobin and DNA
adducts. Acrylamide induces gene mutations and chromosome
aberrations. And it has strong clastogenicity. It breaks
chromosomes.

It is a multi-site carcinogen producing tumors in multiple organs and multiple species of animals. And the World Health Organization has concluded that acrylamide in food is a major concern for human health.

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MR. METZGER: Acrylamide is a potent carcinogen. Based on data from the U.S. EPA IRIS System, OEHHA calculated a safe harbor level of 0.2 micrograms per day. That's a very low level of exposure, making it more potent than such carcinogens as benzene and formaldehyde.

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MR. METZGER: In 2002, Swedish researchers discovered that acrylamide, which was previously known as an industrial carcinogen, that it's present in various cooked foods. And shortly thereafter, scientists determined that its presence in food is a result of the Maillard Reaction, the browning reaction, that transforms asparagine in plant-based foods that contain reducing sugars to the carcinogen acrylamide when heated at sufficient temperatures.

So acrylamide is formed in coffee when coffee beans are roasted, which are at fairly high temperatures. Coffee is the largest source of acrylamide in the adult human diet.

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MR. METZGER: Another reflection of its potency is the margin of exposure, which is -- I think that's actually of European origin. And its technical definition is the point of comparison on the dose response curve divided by the estimated intake by humans. Essentially it reflects the margin between exposure to humans and the exposure level to animals that have been shown to cause harm.

And according to authorities, a margin of exposure of 10,000 is considered safe. You want a 10,000-fold deference between animal exposures that cause harm and human exposures.

And with margin of exposure, the lower the number, the more dangerous. Acrylamide has a very low margin exposure, according to the JECFA, the margin of exposure is just 75 to 300, meaning that exposures to animals just 75 times that of humans are causing harm.

And according to ILSI, they found a margin of exposure as low as 40. So people are exposed to acrylamide at levels that are just 100 times or less than

those that cause harm to experimental animals. So in all the media press that this case -- this issue has gotten, you've probably read, if you follow that stuff, oh, that acrylamide is just present in coffee at trace levels. You know, and your levels are so much lower than those -- thousands of times lower than those that cause harm in animals, it's not correct. We're talking about 100 times less.

And I think because of that, it's that the World Health Organization concluded that acrylamide is a major concern to public health.

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MR. METZGER: Which brings me to CERT's interest.

CERT is the acronym for my client, that Council for

Education and Research on Toxics --

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MR. METZGER: -- which is a public -- California public benefit corporation, whose charitable purposes are education and research on toxic substances. CERT is rather unique among NGOs, because virtually every dollar that CERT receives is distributed as education and research grants, much -- I'd say most of those grants being made to researchers and students at UC campuses.

CERT has focused much of its attention on acrylamide, because acrylamide is the most prevalent

carcinogen in the human diet. And according to generally accepted estimates, the diet is responsible for approximately 40 percent of human cancers. And approximately 40 percent of humans get cancer, so CERT thinks that it's a big important issue that acrylamide is so prevalent in the human diet, this potent carcinogen, and especially in coffee. So CERT has long been at the vanguard of protecting Californians from acrylamide in the human diet.

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MR. METZGER: CERT filed the first case to enforce Prop 65 regarding acrylamide in french fries in 2002. And then CERT co-litigated the next case regarding acrylamide in potato chips with the California Attorney General. Those cases both resolved. And in the french fry case, the manufacturers agreed to provide legally required cancer hazard warnings.

The potato chip CERT considers to be more successful, because the manufacturers of potato chips not wanting to put a cancer hazard warning on packages of potato chips, they decided to get the acrylamide out of potato chips, so they wouldn't have to give that warning, and we now have safer potato chips. And they did that by using an enzyme asparaginase, which prevents the formation of acrylamide.

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MR. METZGER: All right. Well, since 2010, CERT has been litigating a case, which you've probably all read about and have received some -- a little bit of media attention. The case is regarding acrylamide in coffee, CERT versus Starbucks, et al. And the goal of the case is to persuade the coffee industry, the roasters to reduce acrylamide levels in coffee just like the potato chip manufacturers did, so we have a healthier beverage, and we done have a proliferation of warnings.

And after a very short time of eight years of litigation, including two trials that lasted a total of about six months -- and I see some defense counsel here smiling -- CERT prevailed in the case, to the consternation of, I guess, the next speaker from the National Coffee Association.

And it appears to my client anyway that the proposed regulation is a politically-driven effort to overturn the judge's decision. I hope that's wrong, but that's what it appears to be.

My client is of the view that this regulation is totally unnecessary, because the coffee industry can easily reduce acrylamide in coffee, so that the no significant risk level for acrylamide is not exceeded.

There are many techniques available to do this. This was

the opinion of CERT's food scientist expert Dr. Ronald Melnick who testified about published and confidential industrial technologies at the trial.

And so just as the potato chip industry reduced acrylamide, it was able to maintain flavor and taste. We believe that the coffee industry can do so and should do so.

And, of course, getting the acrylamide out, in my client's opinion, is a much better result for public health than warnings, especially for coffee, which is addictive, and people are going to drink despite warnings, just like smokers smoke cigarettes, despite warnings.

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MR. METZGER: I think it's important to note that the European Commission has last year adopted a regulation establishing measures and benchmark levels for reducing acrylamide in food. I won't go through the whole slide here, but -- so at least in Europe, the problem is considered to be serious enough that a regulatory action -- affirmative regulatory action has taken place.

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MR. METZGER: The FDA has not regulated acrylamide levels in coffee. It was going to do so, but the coffee industry claimed that acrylamide could not be reduced in coffee without negatively affecting flavor.

Nestlé, one of the world's largest coffee roasters, met with the FDA to address acrylamide in coffee. And at that meeting, Nestlé intentionally concealed information from the FDA that acrylamide could in fact be reduced in coffee. This is shown by a confidential Nestlé memo that the judge in the CERT versus Starbucks case ordered declassified.

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MR. METZGER: Here's a portion of the document. It says, "Our visit to the FDA was successful in influencing the FDA to use the toolbox approach and against setting guidance values. Nega Beru at the FDA mentioned FDA was going to issue a guidance document for the management of acrylamide which was not issued. We initially had offered to provide more data on acrylamide to the FDA, but on the advice of legal and Nancy Rachman at the Grocery Manufacturers Association we were advised not to provide more data to the FDA, because of the risk of the data being discovered in the event of a lawsuit under Prop 65".

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MR. METZGER: That same document acknowledges that the NSRL for -- set for acrylamide as a carcinogen of 0.2 micrograms per day is so low that all of our products, referring to Nestlé's coffee products, will need a warning

label under Prop 65.

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MR. METZGER: So now the proposed regulation.

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MR. METZGER: "Exposures to listed chemicals in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer".

Magic wand?

No study has been done that shows that. CERT's belief is that there is no scientific evidence to support that whatsoever, and I'll get into that now.

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MR. METZGER: The proposed regulation does not consider that acrylamide is such a potent carcinogen that a cancer warning is required for all coffee. And it does not consider that acrylamide can be reduced in coffee without negatively affecting flavor and taste.

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MR. METZGER: So in 2005, OEHHA itself was considering acrylamide. And it conducted a study, which was published called characterization of acrylamide intake from certain foods. And in this report, OEHHA evaluated whether consumption of coffee results in exposure to acrylamide above the no significant risk level. And this

is what OEHHA concluded in 2005.

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MR. METZGER: This is all quotations. In all cases, the lower bound on acrylamide intake exceeded 1.0 micrograms per day, based on the lower end of the range of consumption, average consumption of coffee with 4.1 ppb or more acrylamide concentration would exceed the NSRL. Since actual Consumption by coffee drinkers is greater, a lower concentration would also exceed the NSRL. Of the individual brewed coffee samples tested by FDA, 19 of 20 had levels higher than 4.1 ppb. All were above 1.9 ppb.

So OEHHA's conclusion is quote, "OEHHA is fairly confident that the NSRL is exceeded for coffee drinkers". That's heavy coffee drinkers, average coffee drinkers, and light coffee drinkers. So that was the quantitative risk assessment that OEHHA did in 2005. And my client finds it very curious that this Initial Statement of Reasons doesn't mention OEHHA's own conclusion that exposure to acrylamide in coffee, per se, for all coffee drinkers exceeds the no significant risk level, and the proposed regulation simply declares it don't.

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MR. METZGER: Yeah. Okay.

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MR. METZGER: So reading through the IARC

monograph -- and the reason I'm going to that is because it appears that most of the rationales, in their Initial Statement of Reasons, are based on the IARC monograph that was issued here. So I'm going to talk a little about the IARC monograph.

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MR. METZGER: So from the Initial Statement of Reasons, yeah, it is clear that the major source of information on which OEHHA relies is the monograph. It was recently published, but reflects scientific research as of May 2016 when the Working Group on Coffee met in France to evaluate coffee. OEHHA misinterprets IARC's conclusions in the monograph in at least three critical respects.

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MR. METZGER: It's more than that, but three really important ones. First, OEHHA claims that quote, "Coffee has not been found to increase the risk of any cancers", unquote.

Absolutely untrue. The monograph nowhere says that. Moreover, the monograph reports significantly increased risks for a number of human cancers, especially childhood leukemia from maternal consumption of coffee during pregnancy. And significantly increased risks of cancer from consumption of coffee have also been reported

for bladder cancer, esophageal cancer, gastric cancer, laryngeal cancer, lung cancer, non-hodgkin's lymphoma, ovarian cancer - that's an IARC major study postdating the monograph - pancreatic cancer, prostate cancer, and total cancer. And many of these are the subject of meta-analyses that have found increased risks.

So OEHHA got that wrong.

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MR. METZGER: Second, OEHHA assumes that inverse associations noted by IARC between coffee consumption and some cancers in the observational studies are causal.

IARC made no such determination. IARC concluded that the available studies -- I should quote, "The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of a causal association between exposure and cancer", unquote.

That is the definition in the preamble for group 3, which is a -- that the agent is not classifiable as to its carcinogenicity. So IARC never concluded that coffee prevents cancer whatsoever.

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MR. METZGER: Had it done so, that would have -- it would have classified it as group 4, which is probably not carcinogenic. IARC did not classify coffee as

probably not carcinogenic to humans.

The third major way in which OEHHA misinterprets the monograph is that -- I just want to say something before I do that. No one at OEHHA read the monograph before the Initial Statement of Reasons was published. As 500 pages, it was first published by IARC on the 13th and this rule came out on the 14th of June. Nobody read it.

All right. Anyway, the third reason OEHHA misinterprets the IARC monograph is that IARC claims that antioxidants in coffee prevent human cancer. But IARC never made any such conclusion. The antioxidant cancer prevention hypothesis is extremely controversial. It has not been accepted by any governmental agency.

Most importantly, meta-analyses of randomized controlled trials show that antioxidant intake actually cause some human cancers and do not reduce the risk of any cancer. Now, those are extremely powerful studies, because randomized controlled trials are -- can establish causality, unlike observational epidemiologic studies, which are subject to massive confounding, bias, and chance.

So when you have meta-analyses of randomized controlled trials that show no reduction in the risk of any cancer from antioxidant intake, but show that antioxidant intake actually significantly increases the

risk of certain cancers, how can one possibly conclude that the antioxidants in coffee prevent -- that's somehow a mechanism by which coffee supposedly prevents human cancer, which IARC itself never concluded.

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MR. METZGER: So all of -- all three of OEHHA's primary conclusion in this Statement of Reasons in support of the regulation are simply flat out wrong. IARC did not conclude that coffee consumption does not increase the risk of any human cancer. IARC did not conclude that the inverse associations between coffee and some cancers are causal. And IARC did not conclude that anti-oxidants in coffee prevent human cancer. IARC -- I'm sorry, OEHHA, not IARC. OEHHA got it wrong on all counts.

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MR. METZGER: Now, I'd like to talk briefly about some post-IARC studies, because we're now two years since the IARC literature review closed in May of 2016. And as we all know, science marches forward.

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MR. METZGER: At the time IARC did its review, there had only been -- the only epidemiology studies that had been published regarding coffee and cancer were observational studies. And as I mentioned, such studies are not controlled, and they're subject to massive

confounding and bias. And because of that, they cannot prove causation.

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That is especially true of nutritional epidemiology studies, because of the enumerable confounding variables in the human diet. And it's because of -- because observational nutritional epidemiology studies are scientifically inadequate to determine causation, and because the coffee cancer epidemiology studies reported conflicting results, IARC concluded that coffee is not classifiable as to its carcinogenicity to humans.

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MR. METZGER: Well, in the two years since IARC completed its review in May of 2016, several epidemiology studies especially designed to determine whether the inverse associations between coffee consumption and various chronic diseases, including cancer, are causal have been published. Kind of a tongue twister.

The bottom line is there are new studies, which show that the inverse associations reported in the observational studies, on which IARC relied, that those are not causal. They do not prevent cancer. They are artifactual.

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MR. METZGER: There have been studies in the last

two years regarding type 2 diabetes, which observational studies show significant reductions from consumption of coffee. Also, Alzheimer's disease, cardiovascular disease, and Parkinson's disease. The observational epidemiology literature for these studies is consistent. Coffee reduces the risk.

So these special new studies designed to eliminate confounding and reverse causation were done, since IARC's review and these studies found no adverse association when -- so those inverse associations are not real. They are artifactual. They do not reflect a prevention of cancer for any cancer or any chronic disease. They -- then these studies disprove the coffee cancer prevention hypothesis. Now, the Initial Statement of Reasons does not mention any of these studies.

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MR. METZGER: OEHHA also claims that coffee is unique.

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MR. METZGER: OEHHA writes, "Coffee is unique, in that it shows reductions in certain human cancers, has not been shown to increase any cancers, and is particular..."

-- "...particularly rich in cancer chemo-preventive compounds".

This statement is incorrect, because the same is

true of tobacco. So coffee is not unique in that regard.

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MR. METZGER: Epidemiology studies - these are observational studies - of coffee consumption have reported decreased risks of breast cancer, endometrial cancer, melanoma, and thyroid cancer. But this does not make coffee unique among chemical mixtures, because cigarette smoking has also been reported to reduce the risk of these same cancers.

That kind of -- that's kind of a head scratcher. Cigarette smoking reducing the risk of cancer?

Well, it actually does. It reduces the risk of these cancers and that's based upon multiple epidemiologic studies and meta-analyses. And it's attributed to an anti-estrogenic effect of cigarette smoke.

So coffee is not unique in reducing the risk of these cancers cause tobacco does it. Smoking does it.

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MR. METZGER: I'm not saying that smoking is good for you.

Okay. So the positive association between coffee consumption and lung cancer is generally thought to be due to residual confounding by smoking, which is highly correlated with coffee consumption. But likewise, the negative association between coffee consumption and

endometrial cancer is probably due to confounding by smoking, because cigarette smoking reduces the risk of endometrial cancer by more than 50 percent, just like coffee. And they're highly correlated. Nobody seems to consider that.

Oh, coffee prevents endometrial cancer. Reduces the risk 50 percent. OEHHA totally failed to consider negative confounding by cigarette smoke as a biologically plausible explanation for the inverse association between coffee consumption and endometrial cancer. OEHHA simply assumed that coffee consumption prevents endometrial cancer.

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MR. METZGER: OEHHA also writes coffee is unique, in that it is particularly rich in cancer chemo-preventive compounds. I think that's basically referring to antioxidants. And that statement is also erroneous because the same is also true of tobacco. Tobacco contains significant concentrations of polyphenols, just like coffee, carotenoids, and also chlorogenic acid, which is what's touted in coffee to be the major constituent that's supposedly good.

So coffee is not unique, because it is particular -- particularly -- I can't say that word -- particularly rich in cancer chemo-preventive compounds.

The same is true of the carcinogen tobacco.

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MR. METZGER: OEHHA also claims that coffee is unique because it has been the subject of very high scientific interest for many years. That statement is likewise incorrect, because it's also true of tobacco.

Among complex chemical mixtures studied, coffee is surpassed only by tobacco for which even more observational studies and experimental studies have been published than have been published regarding coffee.

Well, in fact, the most important and relevant analogy between coffee and tobacco is the addictive nature of these chemical mixtures, which is arise -- rises from the reinforcing properties of caffeine and nicotine.

OEHHA doesn't mention this important similarity between coffee and tobacco, instead relying on incorrect analogies, in CERT's view, for political reasons.

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MR. METZGER: What about OEHHA claim's that coffee is healthy?

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MR. METZGER: So the Initial Statement of Reasons ignores the many carcinogenic and other toxic chemicals in coffee. Of the more than 1,000 chemicals in coffee, only about 50 have been evaluated for carcinogenicity, and

long-term bioassays. And of those evaluated, about two-thirds to three-fourths have shown carcinogenic activity in animals.

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MR. METZGER: Coffee contains caffeine. Caffeine causes several adverse psychological and physiological effects, including mental disorders. These are caffeine intoxication, caffeine withdrawal syndrome, anxiety, sleep disorders, and problematic caffeine use.

These are all diagnoses in the International Classification for Diseases, tenth edition, and the American Psychiatric Association's Diagnostic and Statistical Manual for Mental Disorders, the 5th revision. And these are effects that are established by randomized double-blinded controlled studies. This is not observational epidemiology. This is solid science.

So coffee has several proven adverse human health effects.

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MR. METZGER: Because coffee is naturally bitter, it is typically consumed with sugars, sweeteners, creamers, whiteners, flavorings and other additives, all of which are not healthy. High levels of sugars and saturated fat, of course, significantly increase the risk of cardiovascular diseases, which is itself a major risk

factor for cancer.

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MR. METZGER: And coffee, of course, is a well known, recognized to cause adverse pregnancy outcomes, including reduced fetal weight and growth, pregnancy loss, spontaneous abortion and stillbirth.

By the way, these are -- there's five meta-analyses that are consistent that show this.

Infertility in both men and women, and adverse effects in children and adolescence. And I think it's particularly noteworthy that a major effect of caffeine, and largely from coffee, is reduced birth weight and growth -- fetal growth of infants, because that has also been shown for a acrylamide. There are three major studies regarding acrylamide that used hemoglobin adducts as biomarkers of acrylamide exposure, a very accurate measure of exposure, much better than dietary questionnaires.

These were three different countries did these large studies. And they found that dietary levels of acrylamide - we're talking about human dietary levels - significantly increase fetal retardation and growth.

Acrylamide is, of course, a significant constituent of coffee.

Okay.

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MR. METZGER: What else? The consumption of coffee increases the risk of several chronic diseases as well. Numerous studies regarding bone disease, osteoporosis, and bone fractures, cardiovascular diseases, coronary heart disease, myocardial infarction, stroke, heart failure and angina pectoris.

Autoimmune diseases, rheumatoid arthritis, systemic lupus, erythematosus, and type 1 diabetes gastrointestinal disorders, constipation, gallstones, and gastroesophageal reflux disease.

Urological conditions, urolithiasis, lower urinary tract symptoms, urinary incontinence, and urinary tract infections.

Also, acute cardiovascular events within one hour of consumption. Apparently, coffee is a trigger for acute cardiovascular events.

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MR. METZGER: Well, what about the Dietary
Guidelines Advisory Committee Report. The coffee industry
thinks that this is -- just proves coffee safety. Well,
the report suggests that coffee can be part of a healthy
diet, but it also states that coffee should not be
consumed by susceptible individuals, namely pregnant women
and children, that it can be consumed by healthy people

only in moderation, and that individuals who do not consume caffeinated coffee should not start to consume it for health benefits.

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MR. METZGER: What about -- okay. So the coffee industry also claims that coffee is healthy because it's been consumed for hundreds of years without apparent ill-effect.

Well, that's not a scientific argument. And the absurdity that is shown by butter flavoring diacetyl, which the FDA classified as GRAS, generally recognized as safe. And in the very year that acrylamide was discovered in coffee, this food flavoring was found to be extremely toxic to the human respiratory system causing a fatal lung disease in workers and consumers called bronchiolitis obliterans.

And interestingly, this disease has been diagnosed in coffee roasting workers exposed to diacetyl in roasted coffee.

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MR. METZGER: All right. Well, since I'm a lawyer, you know, I can't go through this and just talk science. I have to talk about a few legal issues here.

But there's only three of them, so bear with me, because I understand that this is a scientific hearing.

It's a scien -- the regulation by the way is pure science. It's a scientific issue, which is why I spent all that time on the science, but I think it's also regulatory. And there are three very important legal issues that should be considered.

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MR. METZGER: First is the people. In 1986, when the voters adopted Prop 65, they intended it to apply to carcinogens in coffee. Pre-election materials of both proponents and opponents of the initiative asserted that the Act would apply to carcinogens in coffee. As a matter of fact, the opposition largely ridiculed the entire initiative because coffee or some certain types of coffee would require a cancer warning but the people voted for it by about a two-thirds majority.

So it's CERT's view that OEHHA therefore proposes to violate the intent of the people of California who, by a large majority, voted for Prop 65 knowing that warnings -- cancer warnings would be required for coffee, if coffee contained carcinogens above the no significant risk level.

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MR. METZGER: The proposed regulation also creates a categorical exemption for all listed heat-formed carcinogens in coffee in the absence of any quantitative

cancer risk assessment. Well, there so far have been two judges who have said you can't do that in your 19 -- around 1990 Judge Ronald Robie of the Sacramento Superior Court, who's now on the appellate court up here, he was the judge assigned to the Duke II case. That was a case brought by the AFL-CIO, and labor, and environmental organizations, a whole slough of NGOs, versus the agency and the State, because the agency had adopted a regulation that exempted all foods, drugs, cosmetics, and medical devices that complied with federal standards without regard to quantitative risk assessment.

And Judge Robie concluded that there can be no categorical exemption. Determined that that regulation violated the Act, Proposition 65 itself, and held it unlawful. And ultimately, that regulation was repealed, because it created categorical exemptions with -- for no significant risk without any quantitative risk assessment.

And that's exactly what this proposed regulation is doing. Hopefully, OEHHA will learn from its prior mistake and not make the same mistake again.

In that case, by the way, on December 23, 1992, there was a settlement agreement of that case signed by the Governor, and the Health and Welfare Agency, which was OEHHA's predecessor. And that settlement agreement provided that quote, "Any provision which is adopted after

the date of this agreement to define the term, 'no significant risk' of the Act for any food...shall be based upon specific numeric standards for the chemical...", unquote. So the proposed regulation violates the Agency's and the Governor's own settlement agreement in that case.

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MR. METZGER: So conclusions. OEHHA's proposed regulation that would simply declare all listed heat form carcinogens in coffee to pose no significant risk of cancer with any quantitative cancer risk assessment whatsoever is grossly unscientific and wrong for many reasons.

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MR. METZGER: First, the proposed regulation is inappropriate and unnecessary, because the coffee industry can and should reduce acrylamide levels in coffee, so that coffee drinkers are not exposed to acrylamide from coffee in excess of the no significant risk level.

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MR. METZGER: Second, the proposed regulation is contrary to OEHHA's own 2005 risk assessment in which OEHHA concluded that all coffee drinkers are exposed to acrylamide in excess of the no significant risk level. If OEHHA is going to adopt a regulation that says it ain't so, it has to explain why -- why it's prior scientific

quantitative risk assessment doesn't apply. You just can't ignore that.

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MR. METZGER: Third, the proposed regulation is based upon OEHHA's erroneous interpretation of the IARC monograph. IARC did not conclude that coffee prevents cancer. It concluded that the available studies were inadequate to determine whether coffee does or does not cause cancer.

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MR. METZGER: Fourth, OEHHA's assertion that coffee has not been found to increase the risk of any cancers is incorrect. IARC found consistent epidemiologic evidence that maternal consumption of coffee during pregnancy significantly increases childhood leukemia.

All the studies that IARC considered suitable showed increased risks of that cancer. They were all consistent, and they were significantly increased. And many epidemiology studies have reported significantly increased risks of other cancers as well.

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MR. METZGER: Firth, OEHHA's assumption that the inverse associations between coffee consumption and cancers are causal is unfounded. IARC did not make such a conclusion, and OEHHA's assumption is contradicted by the

sophisticated new epidemiologic studies post-dating IARC's review which are of a design which can assess causality.

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MR. METZGER: Six, OEHHA's assumption that antioxidants in coffee prevent cancer is unfounded. IARC made no such conclusion. OEHHA's assumption is contradicted by randomized controlled trials and meta-analyses of them, which show no beneficial effect of antioxidant intake, but do show increased risks of some cancers.

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MR. METZGER: Seven, OEHHA's claim that coffee is unique because it is particularly rich in cancer chemo-preventive compounds is unfounded. IARC made no such conclusion. OEHHA's assumption is erroneous because tobacco contains significant concentrations of antioxidants, including chlorogenic acid just like coffee.

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MR. METZGER: Eight, OEHHA's claim that coffee is unique because it reduces the risk of certain cancers is incorrect. Just as consumption of coffee reduces the risk of endometrial cancer, thyroid cancer, and melanoma based on observational studies, tobacco smoke also reduces the risk of these cancers.

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MR. METZGER: Woops, what happened to nine?
Oh, well, I missed one.

Next conclusion. OEHHA's claim that coffee is unique because it has been the subject of very high scientific interest for many years is also incorrect.

Tobacco surpasses coffee for scientific interest of more studies.

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MR. METZGER: Next, that OEHHA's claim that coffee is healthy is incorrect. Coffee has been proven to cause adverse physiological and psychological effects through randomized control trials. And there are recognized diagnoses in the ICD-10 and the DSM-5 for adverse effects of coffee consumption. And coffee in observational studies has also been shown to re -- to increase the risk of multiple chronic diseases, bone diseases, cardiovascular diseases, autoimmune diseases, gastrointestinal diseases, and urological diseases.

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MR. METZGER: I think this is lastly. The proposed regulation is unlawful because, one, it contradicts the intent of the voters that there should be cancer warnings for carcinogens in coffee. It creates -- second, it creates a categorical exemption for carcinogens in coffee in the absence of any quantitative risk

assessments. Third, it contradicts OEHHA's own 2005 quantitative risk assessment for exposure to acrylamide in coffee. And four, it violates the State's agreement in settling the Duke II case that any provision which is adopted after the date of this agreement to define the term no significant risk of the Act for any food shall be based upon specific numeric standards for the chemical.

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MR. METZGER: I guess the final conclusion is that OEHHA should not adopt the proposed regulation, but should instead withdraw the proposal because it is contrary to science and law, and it should do that notwithstanding the politics.

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MR. METZGER: Thank you for your attention. If there's any questions from anyone on the Panel, I'll be happy to address them?

Okay. Thank you very much.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thank you very much.

So now we will hear the second extended presentation from the National Coffee Association. They've submitted, is it, three or four speakers?

Three. Okay. That's what I thought. William Murray, Alan Leviton of Harvard Medical School and Trent

Norris.

MR. MURRAY: Thank you. Can you hear me.

Well, good morning, and thank you for this opportunity to speak here today at this very important public hearing. I will be speaking about coffee.

My name is Bill Murray, and I'm president of the National Coffee Association. The NCA is one of the oldest trade associations in the country. We represent entities in all sectors of the coffee industry, roasters, manufacturers, retailers, nonprofit organizations, brokers, importers and coffee growers.

I should note for the record we are not a litigant or a party to the litigation that was mentioned earlier.

Let me begin by noting that we support

Proposition 65's basic purpose of ensuring consumers are informed about exposures determined by the State of California to cause cancer or reproductive harm. Indeed we've demonstrated a deep commitment to educating coffee consumers about health and safety.

For example, in 2016, we launched "Coffee & Me", a website to provide consumers with information about coffee and health. In providing this information, we've been extremely careful to present only information that is compiled from independent third-party research, research

that we have not funded or been associated with.

Our work in the area of coffee and health is guided by a very respectable group of scientists who together comprised the NCA Scientific Advisory Group, a preeminent authority on coffee science, one of only a few highly respected organizations devoted to this specialized field.

Comprised of top industry experts, members of this group hold collectively decades of experience in a wide spectrum of disciplines, including epidemiology, toxicology, biochemistry, medicine, food safety, and quality assurance.

Because we are an organization guided by science, we believe that if Prop 65's core purpose of warning consumers for exposures is to be achieved in a meaningful way, it is equally important to ensure that consumers are not warned for exposures that do not cause cancer reproductive harm. Indeed, we do believe that this proposed new rule furthers this purposes.

In light of the compelling conclusions and the findings of the scientific community that coffee consumption does not cause cancer, and in some circumstances actually prevents certain cancer, it's enactment would serve to avoid dissemination of information to the public in the form of a warning which

overwhelmingly has been found to be inconsistent with and unsupported by extensive scientific research.

Any outcome other than which -- that which you have proposed would frustrate the legal, scientific, and the policy rationale upon which Proposition 65 is based.

To this end, and as we intend to articulate further in a comment letter, which we'll be submitting, we strongly believe that your proposal is supported by both the weight of scientific evidence and the law.

From a scientific standpoint, this proposal is based on the International Agency for Research on Cancer's recent conclusion that there is insufficient evidence to classify coffee as carcinogenic, and that coffee consumption is actually associated with reduced risk of certain cancers. IARC's review was the most comprehensive evaluation of coffee and cancer to date, and included a process which surveyed more than 1,000 separate scientific studies and produced a comprehensive 500-page report.

Given that this proposed rule is so firmly grounded in scientific research, I am particularly pleased that we are here today joined by Dr. Alan Leviton who will be speaking in support of this proposal. Dr. Leviton is a physician epidemiologist. He's been on the faculty of Harvard Medical School for 47 years. He founded and led the neuroepidemiology unit at Boston Children's Hospital

for 45 of those years. And he's an author of over 400 peer-reviewed publications.

He continues as a professor of neurology at Harvard Medical School. Dr. Leviton's perspective is particularly insightful, as he will provide a firsthand account of what he saw as a credentialed observer of the proceedings of the IARC monograph committee when they met to review coffee, maté, and very hot beverages in Lyon, France in 2016.

Such observers are subject to a thorough vetting process. They must abide by strict rules intended to ensure that they only observe the proceedings and nothing more. Dr. Leviton's expert assessment of the IARC proceedings will confirm that those proceedings provide a rigorous, independent, and thorough foundation and justification for the proposed rule under discussion today.

And even in the short period of time since IARC issue its findings, there have been several peer-reviewed scientific studies, which attest not only to the safety of coffee but to its actual positive impact on various organs in the human body. A recent study of more than half a million people found that those who consumed six or seven cups of coffee a day were 16 percent less likely to die from any disease over a 10-year period than those who

never touch it. These studies further support OEHHA's proposal.

From a legal standpoint, we have the benefit of being represented here today by Trent Norris, a partner at the law firm of Arnold & Porter. Mr. Norris will speak to the legal issues shortly.

But at a basic level, NCA believes that OEHHA's proposal is well within OEHHA's statutory authority, and that this proposal furthers the purpose of Proposition 65 by avoiding inaccurate warnings for a widely consumed and beneficial product.

Now that science has so comprehensively established the facts on coffee, we believe it's appropriate for OEHHA to give citizens confidence in what they're consuming in a way that is based upon and consistent with the overwhelming weight of evidence regarding coffee and cancer.

For this reason, we support OEHHA's determination that exposures to Prop 65 listed chemicals in coffee that are produced as part of, and are in the process of roasting and brewing coffee pose no significant risk of cancer. And we respectfully request that OEHHA adopt the proposal without modification.

I'd like to thank you for this opportunity to be here. This is a privilege. And I'd like to ask Dr.

Leviton, if you would, come and speak to the issues that I mentioned.

DR. LEVITON: Thank you, Bill.

My name is Alan Leviton, and I want to speak today in support of OEHHA's proposed regulation.

Thank you.

Mr. Murray introduced me, and I'm grateful for his introduction.

I was privileged to be an observer of the IARC Review Committee of coffee, maté, and hot drinks conducted in April 2016. Servers can sit in on all meetings of members of the various committees that -- members of the various committees attend. As an epidemiologist, I chose to attend all meetings attended by the epidemiologists.

I was at every single epidemiology committee meeting. As someone who all to frequently receives peer-reviewed comments from people I do not consider my peers, I am sensitive about the qualifications and experience of people selected to be reviewers.

Every single member of the IARC Epidemiology

Committee was highly qualified by virtue of conducting and reviewing epidemiologic studies of cancer that specifically address food and beverage exposures. More than a few were authors of papers reviewed at the meeting.

I was gratified to see how well my epidemiology

colleagues performed their due diligence. Every epidemiologist had done her or his homework. They, as a group, were methodical in their presentations, tables and figures of all kinds, group studies of each organ by sample size whether retrospective or prospective, the quality of the data, attention to potential confounding, and overall rank of quality. It was impressive to see this done for every organ.

The rankings of papers based on overall quality is essential to the process of what's called weighing the data, or weighing the evidence.

Indeed, doing this is what changed the IARC assignment of coffee from group 2B in 1991, which is -- classifies it as possibly carcinogenic to humans, to group 3 in 2016, which is defined as inadequate evidence in humans for cancer.

For example, case control studies of cancer obtain information about coffee consumption, cigarette consumption, and other potential exposures from people who have already been made aware of their disease. Because some people, who develop tobacco-related malignancies, are more likely than others to underreport their tobacco exposure, case control studies of tobacco related malignancies are prone to bias.

Contrast cohort studies which obtained data about

exposure, years and even decades before the diagnosis of cancer, are deemed of much higher quality compared to case control studies. Prospective, long-term cohort studies are considered much less prone to bias.

Back in 1991, when IARC previously reviewed coffee, the only studies of the relationship between coffee consumption and some cancer sites were case control studies.

By 2016, however, large-scale, well-conducted, long-term cohort studies unavailable in 1991 were available to the working group. Not only did the working group in 2016 give more weight to these studies - and that's the word that the working group used, "weight" - they also gave the greatest weight to the largest studies.

The prominent discrepancy between findings of case control studies and the large scale, long-term prospective cohort studies prompted the working group to conclude that the findings of some case control studies were most likely due to the confounding of tobacco smoking that had not been adequately controlled.

My impression in 2016 was that if the working group did not have the old case control studies to contend with, it would have concluded that the evidence suggested lack of carcinogenicity in coffee consumption.

I was also gratified to see how well my

epidemiologic colleagues performed their assessments and made judgments so fairly. They were as neutral about the findings as they could be. Equipoise is the word that I would use to describe the Committee. Even authors of relevant studies were reluctant to paint their own studies in a more favorable light than they deemed appropriate.

I was delighted to hear one of the reviewers say
I fully recognize that the major limitation of my study is
the potential for recall bias. All in all, I felt that
the quality of the reviewers and the review process was
very high and unquestionably fair.

For these reasons, OEHHA's reliance on this very detailed and unbiased review process is justified and appropriate from a scientific standpoint.

I'm grateful to members of the Committee here for the opportunity to encourage OEHHA to continue with the plan to clarify that cancer warnings are not required for coffee under Proposition 65.

Thank you very much for listening so patiently to me. Thank you.

MR. NORRIS: Thank you, Alan.

Good morning. I am Trent Norris. I'm a partner with the law firm or Arnold and Porter. And in the past 25 years, I've represented over a thousand companies in lawsuits and regulatory matters concerning Prop 65. I'm

here today on behalf of the National Coffee Association.

And as Bill Murray explained earlier, NCA strongly

believes that OEHHA's proposal is supported by both the

weight of scientific evidence and the law.

As the agency tasked with implementing Prop 65, OEHHA is empowered to quote, "Adopt and modify regulations, standards, and permits as necessary to conform with and implement Prop 65 and to further its purposes".

From a legal standpoint, the rulemaking here is on solid ground. It is well within OEHHA's statutory authority. And it furthers the purpose of Proposition 65 by avoiding unnecessary warnings for coffee, a widely consumed and beneficial food.

Two cases demonstrate OEHHA's broad statutory authority to enact the rulemaking here. The first case Nicolle-Wagner versus Deukmejian from 1991 confirmed OEHHA's statutory authority to adopt regulations that provide complete exemptions for exposures to even very broad classes of chemicals in foods and beverages.

In the Nicolle-Wagner case, the court of appeal upheld a regulation enacted by OEHHA's predecessor agency that exempted naturally occurring chemicals in food from Proposition 65's warning requirement.

The court determined that OEHHA's exemption for

all naturally occurring chemicals would further the statutory purpose -- quote, "...would further the statutory purpose in safeguarding the effectiveness of warnings which are given, and in removing from regulatory scrutiny those substances which pose only an insignificant risk of cancer or birth defects within the meaning of the statute", closed quote.

In the second case, much more recently, Mateel Environmental Justice Foundation versus OEHHA, in 2018, just earlier this year, the court of appeal confirmed OEHHA's statutory authority to adopt regulatory safe harbor levels for certain listed chemicals.

The safe harbor regulations have provided important guidance to persons in the course of doing business, i.e. the regulated community, so that they can either reduce the level of chemicals in their products or provide warnings. That reduces the number of warnings that are provided simply to prevent litigation without reference to whether they are required under Proposition 65.

It's well within OEHHA's statutory authority to enact the rulemaking here. OEHHA's proposal is based on extensive scientific data from the International Agency for Research on Cancer, which the State's qualified experts appointed by the Governor has determined to be an

authoritative body for the identification of listed chemicals.

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Unlike other proposed regulations that have been challenges os overbroad Categorical exemptions, OEHHA's rulemaking is narrow, precise, and based on a robust body of scientific studies that are specific to the chemicals and the product at issue.

Indeed, under the cooking provision adopted by OEHHA's predecessor, a court has the authority to determine that an alternative significant risk level is appropriate for a chemical created in cooking food.

Likewise, OEHHA retains that same authority, and could state a numerical level for an individual chemical, such as acrylamide, created in cooking a type of food such as coffee, where it's supported by quote, "sound considerations of public health". And that's true even if that level is higher than what OEHHA's default assumptions or even more scientifically appropriate assumptions might support as the significant risk level.

Here, such sound considerations clearly exist, not only due to the risk of overwarning, but also due to the overwhelming strength of scientific evidence showing that drinking coffee does not increase the risk of cancer if humans.

Significantly, nothing in Proposition 65 or its

implementing regulations indicates that a quote, "No significant risk level", closed quote, must be stated numerically or even be finite. OEHHA's rulemaking is the practical equivalent of a finding that the no significant risk level is infinite for carcinogens in coffee that are produced as part of and inherent in the processes of roasting and brewed coffee.

It does not affect the listing of these chemicals, which is controlled by statutory requirements, but instead it interprets and implements the expressed statutory exemption from warnings where quote, "The exposures poses no significant risk assuming lifetime exposure at the level in question", closed quotes.

In Baxter Healthcare versus Denton, a 2004 case, the court of appeal approved of a trial court finding that any level of exposure to a chemical - the chemical at issue there - requires no Proposition 65 warning, because that chemical, although properly listed on the basis of animal studies, does not affect humans in the same manner.

The Baxter court essentially adopted an infinite safe harbor level for the chemical, based on the strength of scientific evidence. Just as a court is permitted to do this, so is OEHHA.

Finally, the rulemaking would further the purpose of Proposition 65, because it would clarify that warnings

are unnecessary for chemicals in coffee that are inherently created by the roasting or brewing process. But consistent with the original intent of the law, it would not exempt chemicals that may be intentionally added to coffee. This is the same distinction that's set out in OEHHA's regulation on naturally occurring chemicals in food, which has been upheld as valid in the face of a challenge.

So in summary, OEHHA clearly has the legal authority to adopt this proposal. And accordingly, the National Coffee Association respectfully requests that OEHHA adopt the proposal without modification.

Thank you.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thank you.

So we have now three speakers who have filled out blue cards. So I will -- so we will hear from them. If you want to speak and haven't filled out a blue card, I recommend that you do so, and you can give it to Monet Vela. If you want to speak, but prefer not to fill out a blue card, that's fine. What I'll do is after all the speakers who've filled out cards have spoken, I'll ask if anyone else would like to speak.

So then the next speaker, and we are asking that you limit your remarks to five minutes, is Jeffrey

Margulies of NRF. I believe that's National Retailer

Foundation, but you can correct me, as well as California Retailers Association.

MR. MARGULIES: Thanks, Alan.

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Actually, the NRF is Norton, Rose, Fulbright. I did not have enough room to put all of that on one card, so I apologize.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Well, that's why I shouldn't assume.

MR. MARGULIES: That's not a problem. So, yes, my name is Jeff Margulies. I'm a partner with the law firm of Norton, Rose, Fulbright. And I'm here today on behalf of the California Retailers Association with whom I've worked for years on Prop 65 and other issues.

I'm not here to talk about the merits of the proposed rulemaking. I will leave that to the roasters, and to OEHHA, and Mr. Metzger. I want to talk about the process a little bit, and I will be brief.

Between the court ruling, this proposed rulemaking, and the extensive press coverage of both, there's rampant confusion in the marketplace. Retailers are hearing contradictory messages about whether warnings are required for exposures to chemicals in coffee, particularly acrylamide.

As of today, Judge Berle has shown no indication of any willingness to stay the litigation pending the

outcome of this rulemaking, and expressed at a recent hearing that he considers it speculative whether this Agency will ever adopt a rule. And he intends to hear CERT's motion for permanent injunction on September 6th.

If it's granted, and if the case isn't stayed, that would only increase the amount of confusion in the marketplace. For that reason, California Retailers

Association urges OEHHA to complete the rulemaking process with all deliberate speed and to adopt the proposed rulemaking to ensure that consumers are not given misleading information about coffee and cancer.

Thank you.

CHIEF DEPUTY DIRECTOR HIRSCH: Thank you.

Next speaker is Robert Donohue representing Canteen.

MR. DONOHUE: Good morning. My name is Robert Donohue, and I'm an employee with Canteen here in Sacramento.

As a member of the convenience service industry, I support the OEHHA proposal to add a provision to the code, which will effectively exempt coffee from Prop 65's warning requirements. The convenience service industry includes vending, micromarket, office coffee, and pantry service channels. It has a two billion economic impact on the state of California, and is responsible for over

10,000 jobs in the Golden State.

I agree with your assessment that exposures to Prop 65 listed chemicals in coffee that are produced as part of and in the process of roasting coffee beans and brewing coffee pose no significant risk of cancer.

OEHHA is correct to side with the scientific consensus, according to the federal government's own dietary guidelines, moderate coffee consumption is not only unassociated with the increased risk of major chronic diseases, but it can actually be incorporated into healthy living styles to mean good health and reduce the risk of chronic disease.

The World Health Organization dropped coffee from its list of possible carcinogens two years ago, noting that moderate coffee consumption can actually lower cancer risk, because coffee beans contain healthy antioxidants.

Most recently, two studies published in the Annals of Internal Medicine tracked the coffee intake of more than 600,000 individuals for over 16 years.

Researchers concluded that coffee drinkers experienced lower risk of health -- of death from heart disease, respiratory disease, diabetes, stroke, and cancer.

Coffee remains on Prop 65's list of flagged substances because of acrylamide, a flavorless chemical

naturally produced when coffee beans are roasted.

Although mega doses of acrylamide have been linked to cancer in rodents, the National Cancer Institute has found no consistent evidence that dietary acrylamide exposure is

5 associated with the risk of any type of cancer in human

6 beings.

Prop 65 warnings would impose onerous labeling requirements on businesses like mine that are located in California and supply coffee to California. Mandated signage could leave us vulnerable to frivolous lawsuits which could lead to increased consumer cost. Prop 65 threatens California's convenience service industries at large whose vendors bring coffee as well as tea, water, fresh food, and more to employers and employees throughout the state.

Prop 65 would negatively impact the industry for which employs thousands of individuals in the state and brings in billions of dollars in revenue to California.

OEHHA should move forward with relieving Prop -- or relieving coffee of its Prop 65 burden.

Thank you.

CHIEF DEPUTY DIRECTOR HIRSCH: Thanks.

Just a point of clarification. Coffee itself is not on the Prop 65 list. Obviously, the focus of this regulation is the cancer impacts of listed chemicals that

happen to be in coffee as a result of roasting or the brewing processes.

So next speaker -- my apologies if I don't get your name right -- John Hornung.

MR. HORNUNG: You said it perfectly.

CHIEF DEPUTY DIRECTOR HIRSCH: All right.

MR. HORNUNG: My name is John Hornung. And I am here representing myself as a Californian. I do work with a company called Incasa, Inc., which does handle coffee as flavoring. But again, I'm representing myself here as a Californian.

I was born in Merritt Hospital in Oakland. I was raised in Contra Costa County. I've lived throughout various counties in California. And I'm actually fifth generation Californian on both sides of my family.

Back in -- when Prop 65 was first proposed, I enthusiastically voted for it. I was happy to vote for it. As Californians, we're at the forefront of a healthy lifestyle, and wanting to know what we ate or drank was good for us or if it was not. We were enthusiastic about having the opportunity to vote for something that we thought could protect us from potential cancers.

And this is why I want to thank you today for your proposal, because I think that your proposal is exactly in the ballpark of being the original intent of

those of us Californians who voted for Prop 65. We wanted to know if something was going to be bad for us. We did not want to -- we also wanted to know if something was going to be good for us.

And we don't want labels on products that are actually healthy for us that might, in some way, cause us to have apprehension about consuming them.

Now, the science has been overwhelming. Because I have been associated with the coffee, I played -- I paid really close attention to the science over the years. It's been overwhelming. We see 30-year studies with large cohorts of 30,000 people in Czechoslovakia, Italy et cetera, et cetera. And the recent conclusions by the International Association for the Research of Cancer, the World Health Organization arm, the FDA, et cetera, prove again and again that the scientific community worldwide is the consensus that coffee is very healthy for you.

In fact, many studies by respected scientific organizations in their conclusions state coffee drinkers live longer. Flat out. Coffee drinkers live longer.

So while there is all sorts of epi -- excuse me, contradictory statements made because of associations with different studies and different approaches to the studies that were taken, overall the scientific community is of the opinion that coffee drinkers do live longer.

But not only do the live longer, we've also seen studies that have come out as Mr. Metzger mentioned about prevention of Parkinson's, Alzheimer's, diabetes in overwhelming numbers. In other words, not only do coffee drinkers live longer, but they live healthier and better lifestyles. So it's quality of life as whether -- as length of life.

So for this reason, I really want to thank you and really applaud you. And I really do encourage you to continue forward and get this regulation passed as soon as possible.

Thank you.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thanks.

So the last speaker who has submitted a blue card. And, I'm sorry, I think I'm going to butcher your name, even though I shouldn't. But Adam Riegel, Rejel from the California Chamber of Commerce.

MR. REGELE: Adam Regele on behalf of the California Chamber of Commerce.

I'll keep my statements short. We're in strong support of the proposed regulation. Thanks.

(Laughter.)

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. So that was the last of the blue cards.

Is there anyone who would like to speak?

Go ahead.

2.4

MS. LARSON: Sandra Larson with NAMA and CAVC. We are the trade association for the convenience services industry. And I concur with what my colleague Robert Donohue testified to. We are very much, both of our organizations, in support of the proposal.

Thank you.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay.

Thank you.

Anyone else has any thoughts to share with us?

Okay. Hearing none, I hereby close this public hearing.

And again, as a reminder, we will accept written public comments until 5:00 p.m. on August 30th, 2018. You can submit your written comments electronically through our website at oehha.ca.gov/comments. If you'd like to snail mail us your written comments, you can certainly do that. You can send them to Monet Vela, M-o-n-e-t, V as in Victor E-l-a, at the Office of Environmental Health Hazard Assessment, P.O. Box 4010, Sacramento, California, 95812-4010. And all that information is on our website. Or if you like, you can even fax them to us, (916)323-2610.

And again, if we finalize this regulation, we will under State law provide written responses to the

comments we've heard today as appropriate, as well as the written comments that we get. So thank you very much for your interest. (Thereupon the Office of Environmental Health Hazard Assessment public hearing adjourned at 11:39 a.m.)

CERTIFICATE OF REPORTER

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 Office of Environmental Health Hazard Assessment public meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and 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 meeting nor in any way interested in the outcome of said meeting.

IN WITNESS WHEREOF, I have hereunto set my hand this 27th day of August, 2018.

fames & The

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