STATE OF CALIFORNIA
DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC)

PUBLIC WORKSHOP ON POTENTIAL HEALTH AND SAFETY IMPACTS OF CHEMICALS IN NAIL PRODUCTS

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WORKSHOP PRESENTATIONS AND DISCUSSION

MARCH 2, 2017
9:01 a.m.

MS. PAPAGNI: We’re going to go ahead and get started, it’s 9 o’clock. Good morning, everyone.

I want to thank all of you for attending today, both in person and via webinar. We have about seventy people attending over the webinar today which is great. Great attendance.

My name is Christine Papagni. Many of you have communicated with me or some of my colleagues over the past few weeks or months or participated in the webinar that we, the Safer Consumer Products Program, hosted on November 15th. The goal of today is essentially to continue those conversations and we encourage you to share with us and provide information.

Due to interest, we have a full day of speakers and we’ve also allotted time after each presentation for both questions of the speakers and comments to DTSC; so, we’re encouraging you to share with us. And with that, I’d like to introduce our moderator for the day, Marcia Rubin.

MS. RUBIN: Thanks, Christine. I’ll be moderating the day and we have a lot of speakers. Thank you all for taking the time to participate here with us today and on the webinar.

I’m going to cover a few housekeeping points and
ground rules before we get started. I want to ask the 
speakers when you come up to speak, please go around the 
sides, there’s a lot of technology here, we’re trying to 
make sure that everyone gets to participate.

We also have a court reporter here. She’s 
recording the day so that we can capture all of the great 
speakers that we have and all of the comments and questions 
that we get from people.

I’m going to ask you to silence any noise emitting 
devices, smartphones, tablets, watches, anything that might 
disrupt our workshop today. And limit your cross 
conversation. Because we have people participating on the 
webinar, we want to make sure that everyone gets heard and 
so if you’ll keep the cross conversation limited. If you 
need to have some, take it outside.

We also want to ask you to be brief in your 
comments and questions. There’s a lot of information to be 
shared and, there’s also going to be more opportunity for 
dialog, so we’re going to follow our agenda very strictly 
and try to make sure we get as much dialog as we can in 
today.

For people joining us via webinar, I want to share 
with you if you don’t see anything happening on the screen, 
that’s a period where we’re going to be having question and 
answers and dialogs so you can participate in that by typing
in to your dialog box in the webinar and we’ll make sure we try to get to as many questions or comments as we can.

The restrooms are upstairs and at the end of the hall past the auditoriums; if you just go to the end of the hall, they’re right there and you’ll see signs for that.

We are only using these two doors today for entrances and exits so don’t use this door. In the event of an emergency, our meeting point is going to be Cesar Chavez Park and the cross streets for that are I and Tenth, it’s directly diagonal to our building.

With that, we’re going to -- we have built-in breaks on our agenda, but if you need to take a break, please do so and try to be quiet as you can, so we can keep the tone of the workshop going.

With that, I want to introduce our esteemed director Barbara Lee. She’s here to welcome you today.

Thank you.

MS. LEE: Good morning, everyone. I hope you can understand me. I’m coming off of a kind of an unfortunate bug. All of you who are participating on the webinar are in much better shape than the folks who have to share this space with me, but I’m trying not to shake any hands or cough on anyone, so bear with me.

I really appreciate the fact that so many of you have turned out here in person to talk with us and also that
you have participated via the webinar. This is a wonderful 
opportunity for DTSC to gather information to expand our 
understanding and to build the relationships that we need to build in order for this to be a successful program.

Today is focused on nail salon products and what’s in them and how they’re used and potential exposures to them. You’re going to hear from a variety of different perspectives on this and that’s the goal of our meeting today. You have a wealth of talent in this room, you bring a wealth of talent to this room. We have representatives like Catherine Porter and Tom Myers who are here from the Healthy Nail Salon Collaborative and also the Personal Care Products Council. We also have some exciting presentations including a webinar presentation from Diana Ceballos from the Harvard School of Public Health. There is a broad scope of information exchange that we’re hoping is going to happen. And we want to hear all these unique perspectives.

We’re collecting information; we don’t have an endpoint in mind yet. And that’s the beauty of this program. It’s my personal feeling that our Safer Consumer Products Program, Dr. Meredith Williams, Karl Palmer, and all of the staff who work on it embrace this model of collaborative working. And it makes the program tremendously strong. I’m thrilled that I get to be here, at least for part of it, and share this with you. Coming out
of today we will probably have more questions than we have
going in to it now. That’s our goal, so please help us open
this topic up. Help us dive into it deeply. Share your
thoughts and ideas. Share your questions. You don’t have
to bring us answers, we’re looking for all the right
questions to ask so that we move forward with the most
comprehensive set of information that we can.

It’s also really important to me that our topic
today addresses an issue that is personally very important
to me which is environmental justice. Broadly, DTSC has
embraced environmental justice and our obligation to protect
all Californians regardless of their income status, their
ethnic background, or any of the other factors that makes
each and every one of us unique.

In this particular instance, the people who likely
bear the most significant exposure to these products are
largely immigrants. These are women, many of whom speak no
English. They come to us from Asian countries, they work in
shops where they are potentially exposed all day long and
have not always had the best recourse to have their concerns
heard and addressed. And this is an opportunity for all of
us to try to understand those concerns, to look at the tools
that we have to address those concerns, and to give them
protection that they deserve. And it isn’t clear to me yet
what shape that’s going to be. I don’t think the staff I
have working on this issue know yet what shape that’s going
to take. But we do know the most critical first step is
listening and understanding and being receptive to an entire
range of opportunities that are out there for us to be
proactive and be protected.

Again, I am so happy that all of you are here,
that those of you who are participating via the webinar are
putting the time into this effort. We want to move forward
with as big of a tent as we can and with the best possible
information. Thank you for helping us to do that.

MS. RUBIN: Thanks, Barbara.

Our first two speakers of the day are -- are a
part of our DTSC team and we’re going ask you -- we’re going
to have an opportunity for questions and comments following
their presentations, but we’re going to ask you to hold your
comments until both of the presenters have finished.

First up we have André Algazi, he’s the lead for
the chemical product evaluation team here. And he’s going
to give you an overview of the Safer Consumer Products
Program and the nail products efforts that we’ve been
undergoing here.

MR. ALGAZI: Hi, good morning. Thank you all
again for being here. And welcome.

As Marcia just stated, what I’d like to do is sort
of provide a little bit of context for what we’re talking
about today and today’s agenda. And I wanted to start by reminding us of the regulatory framework for Safer Consumer Products. Many of you will be familiar already and it would just be sort of a reminder. For those of you who aren’t, it’s a very brief introduction.

We’re working under the framework of the Safer Consumer Products regulations, and there are four elements of that framework. The first is Candidate Chemicals, and the regulations themselves contain a compilation of 23 lists of chemicals that have been identified based on either their hazard traits, for example IARC carcinogens. And there’s also a group of lists that are included because of their chemicals that have been identified for exposure potential. For example, the Biomonitoring California list of priority chemicals. There are 23 lists, 15 of the hazard lists, hazard trait chemicals, and 8 that are based on exposure potential.

The second element of the regulatory framework is Priority Products and that’s really where we are right now. We’re in somewhat early stages of identifying our next possible Priority Products. And I’ll talk a little bit more about that element in a moment.

And then thirdly, once we’ve identified a Priority Product and adopted regulations to list it formally as a Priority Product, the manufacturers of that product are
required to conduct an Alternatives Analysis in which they identify potentially safer alternatives to using the Chemical of Concern and sort of answer the question, is it necessary to use this chemical or not.

And then, finally, the fourth element is the regulatory response element, in which the regulations provide a menu of options. And it really is dependent on the Alternatives Analysis, what the alternatives identified were, what the factors that were compared, and what the outcome of the analysis is. As Director Lee said, we really haven’t identified the products yet and even if once we do, we won’t have a predetermined regulatory response in mind.

In this second of the four phases, we are working under our three-year work plan and the regulations say that every three years we adopt a work plan that identifies the categories from which we will choose Priority Products during that three-year cycle.

With the current work plan, we’re in year three of the 2015 to 2017 Priority Product work plan. There are five policy priorities that we used and we’ve identified seven product categories in the work plan. And for each of those product categories, we provide some example chemicals that we identify. It is not an all-inclusive list of all the Candidate Chemicals that might be in the product categories, but some examples.
The regulations provide the overarching criteria for how we select a Priority Product -- the key prioritization principles. And, they are, that whatever the Priority Product is, there needs to be potential for exposure to the Candidate Chemical in the product. And secondly, there has to be potential for that exposure to contribute to or cause significant or widespread adverse impacts. That’s the overarching principle.

That’s a really brief overview of the regulatory framework. Now I want to talk a little bit about why we are talking about nail products today. And really our interest in products in this category is not new, we’ve had a number of activities around nail products, most recently in 2012, and Dr. Sciullo will talk a little bit more about this. We undertook an investigation in which we took some samples and distributors in the Bay Area of products including ones claiming to be free of certain chemicals and did some analytical testing and found that a number of the products claiming not to contain formaldehyde, toluene, or dibutyl phthalate actually did sometimes contain one or more of these chemicals. And we also, at that time, detected some of the other chemicals that are now on our Candidate Chemicals list in those products.

Currently, we have some new legislation that we’re involved with which is Assembly Bill 2125, “The Healthy Nail
Salon Recognition Program." And this bill calls upon DTSC to develop guidelines for local healthy nail salon recognition programs that include things like best practices, chemicals that they shouldn’t used if they want to be certified, things like that. We have a January 1st, 2018 deadline to complete these guidelines. We’re also going to be working with existing local healthy nail salon recognition programs. And we’re also going to be working on some outreach elements.

If you’re interested in that effort, it’s not directly related to the Safer Consumer Products framework but, because it affects the same set of products we’re talking about today, I wanted to mention it. And there’s a link to the actual legislation at the bottom of this slide.

There are a couple of other recent bills that were also signed in 2016 related to nail salons having to do with information availability to employees and language access. These are the two bills, AB 2437 and 2025. And, again, I’ve included links to those two.

I mentioned that our Priority Product work plan has seven product categories which are shown on this slide. And the nail products fall into this one, the beauty, personal care, and hygiene products. It’s a subset of that category.

And I also mentioned the five policy priorities.
And at least four of those five policy priorities which we used in selecting the categories in the work plan and that we’re using as we look at personal care, beauty, and hygiene products now have been met. Products where there’s clear pathway to exposure to a Candidate Chemical which we’ve found that there is for products in the nails category. Products that contain chemicals which are found in indoor air and dust and that’s also the case for this group of products. Products containing chemicals detected in biomonitoring studies is the third policy priority. And products that have a potential to impact workers and children. At least four of these policy priorities are met by nail products.

The scope of our conversation today in our presentations is the broad range of nail products including ones for home use as well as salon. We’re seeking information on what the chemicals are, their toxicity, and their potential to expose people. We’re interested in formulations, especially products that have claims of being free of certain chemicals and what the alternative chemicals might be. And we’re also interested in what initiatives have been undertaken by industry manufacturers to improve the safety of nail products.

We are looking for information on the use of these potentially hazardous chemicals, what their functions are,
how prevalent they are, what the safer alternatives or potentially safer alternatives are either under development or already in use. And as the director said, another major goal today is to facilitate dialog among experts from all of the different sectors that make up our group of stakeholders.

We know that the landscape of nail products is changing and has been over the last number of years, and we’ve noted that a number of products are making claims of being free of various chemicals, I mentioned the 3-free earlier which were products purportedly free of dibutyl phthalate, toluene, and formaldehyde. There are also now products claiming to be free of 3, 4, 7, and 9 different chemicals, and 10. And, again, Dr. Sciullo will give a little more information about those.

Again, we’re interested in what’s being used to replace these chemicals when they’re free of them. And are they Candidate Chemicals and what do we know about their safety relative to the chemicals that have been removed.

Again, in the four steps or the four elements of the regulatory framework, we’re really in the second one which is Priority Products. And we’re kind of ending our public engagement phase, although it’s not over yet. We’re actually going to be accepting information and comments through the 17th of March. The deadline was February 28 and
it’s been extended to the 17th of March so if you have
information or comments you’d like to share with us through
our Web portal CalSAFER, you still have a couple more weeks
to do that.

We started off this phase with our webinar on the
15th of November, and published our background document and
our stakeholder questions, so this has been ongoing for a
number of months. Based on the information that we get from
all of you and other venues, we will be refining our
research topics to look at this category through the lens of
those key prioritization principles, potential for exposure
and potential for exposure to contribute to or cause adverse
impact, and identifying products that might be potential
Priority Products.

Again, once we’ve made those kinds of
identifications, we would then embark on a rulemaking
process which is a public process. We are still early in
this second of the four stages of the process.

We do want to stay engaged with all of you and
this slide and the next one have some contact information.
If you’d like to follow our future public engagements,
announcements, things like that, you can subscribe to our e-
list, there’s a link on this slide. We have a dedicated
Safer Consumer Products email box that can be used for
questions and inquiries, you can contact our Public
Information Officer Ben Edokpayi. If you’re from the media and you’d like to make an inquiry. You can contact me or Christine Papagni with technical questions and Heather Kessler if you’d like to request a meeting.

And, again, we’ve extended the deadline for submitting information and comments through CalSAFER to March 17th. And this slide also has a link to the CalSAFER portal.

Again, I thank you for being here, for engaging with us, for sharing your knowledge and expertise. I’ll hand it back to Marcia.

MS. RUBIN: Now I’m going to cue up the next presentation. The next speaker from DTSC is one of our Ph.D. staff toxicologists. He is going to discuss in more detail the potential health and safety impacts of chemicals in nail products. And, with that, Dr. Eric Sciullo.

DR. SCIULLO: Thank you, Marcia.

Good morning. And welcome to this part of the workshop entitled, “Potential Health and Safety Impacts of Chemicals in Nail Products.”

I’d like to start with a little bit of an overview in terms of how we’ve arrived at the place where we’re at today and I’ll be going into these bullets with a little bit more detail as we move forward in the talk. In 2012, DTSC was involved in a sampling study of nail products looking at
ingredient claims and seeing what exactly the constituents turned out to be. Following after that, there were a number of articles that came out that garnered national interest in this topic, most notably one from the New York Times which highlighted exposure concerns to workers to chemicals within nail products.

In addition, in recent years, a number of healthy nail programs have been established throughout the state of California and multiple counties. And here we are, with DTSC’s Safer Consumer Product initiative which has given us the capability to evaluate chemicals across a wide variety of categories in terms of potential hazards and exposure. And as André just mentioned, a number of legislative bills have recently passed in the state of California, most notably AB 2125—“The Healthy Nail Salon Recognition Program.” And finally, our stakeholder engagement efforts which is where we’re at right now and we hope to have a nice discussion here.

In 2012, DTSC underwent a nail product sampling study. It was limited in scope to salon products from San Francisco Bay area distributors and no retail products were sampled. The samples were randomly collected and there were 25 samples taken. Approximately half, 12 of the 25 products claimed to be free of at least one of the toxic trio chemicals. And the toxic trio refers to formaldehyde,
toluene, and dibutyl phthalate. And I’ll get into those more soon.

Ten of the 12 products with toluene-free claims contained toluene as high as almost 18 percent. Some products claiming to be free of toxic trio had actually high detections of dibutyl phthalate compared to products that weren’t making any such claims. And, finally, triphenyl phosphate was identified in some products as a chief alternative plasticizer for dibutyl phthalate.

DTSC’s current efforts on nail products were initiated by the 2015-2017 Priority Product work plan under the general category of beauty, personal care, and hygiene. We were able to evaluate chemicals in nail products and quickly identified the obvious toxic trio formaldehyde, dibutyl phthalate, and toluene. In addition, a number of other Candidate Chemicals exist that may or may not be within nail products and are potentially of interest and of concern.

Why nail products? Well, there’s a wide variety of chemicals and an incredible array of categories. And in particular, we have concerns regarding salon workers and also consumers. But nail salon workers in particular because overwhelmingly a majority of salon workers are women of color and reproductive age and they represent an important niche market for Vietnamese immigrant workers.
And as a result, they often have language barriers, limited education on chemical exposure from products, limited use and/or vulnerability of personal protective equipment, and they often work in excess of 8-hour days and 40-hour workweeks. In addition, pregnant women and children are also of concern with regard to nail product.

The exposure potential of these chemicals varies depending on the chemical and the product, but most products contain volatile chemicals which have the potential to off-gas into indoor air and be a potential inhalation exposure concern for humans. Also, these products can contain chemicals that may be absorbed dermally across the skin. Exposure is likely affected by poor ventilation or lack of personal protective equipment, long workdays and weeks, number of clients in a given day or week, weather conditions, building properties, and there’s a wide range of product types and categories; so, obviously, this will influence exposure.

What types of products? Well, this list, includes, but is not limited to, nail polish and coatings, base adhesives, nail hardeners, nail conditioners, artificial and gel nails, nail product thinners, nail polish removers, and nail art.

Here is a summary table describing the toxic trio of chemicals and triphenyl phosphate which was one of the
chief alternative plasticizers for dibutyl phthalate that
was identified in our 2012 sampling study. And, I’m going
to go into these in more detail here, but I just put them up
here to get an overhead view.

I’d like to start with formaldehyde. Formaldehyde
is used as a preservative, an antimicrobial, and a nail
hardener in select products. The FDA has set a
concentration limit at 5 percent for nail hardeners. It’s a
human carcinogen, a respiratory toxicant, an eye irritant,
and can initiate dermal or allergic reactions in some
populations.

What is formaldehyde? Formaldehyde has a complex
history in terms of how it’s described and even the
terminology in the language. I think it’s worth kind of
going into what is formaldehyde exactly.

Formaldehyde is a gas, first, at room temperature.
And it’s highly reactive with water. When it reacts with
water, it forms methylene glycol. And methylene glycol has
distinct physical-chemical properties from formaldehyde;
however, the U.S. EPA, ATSDR, the FDA, and the Scientific
Committee on Consumer Safety treat them interchangeably with
respect to labeling, exposure, and hazard. Formalin is
another name you’ll see used to describe formaldehyde and
formaldehyde-type solutions. It’s an alternative name for a
percent solution of methylene glycol, and I think has its
genesis within laboratory sciences.

There are also formaldehyde releasers and there are also tosylamide formaldehyde resins which are related to formaldehyde but they are also very distinct in their own right. Again, their purpose is usually to release or provide some sort of long-term preservative for product stability.

I’ve created some questions of interest that I don’t really expect to be answered, but I hope that maybe they’ll come up through the course of the day through discussion, but these are some of the topics of interest that we have. How is formaldehyde added into nail products and at what concentrations? Does free formaldehyde escape from nail products into indoor air, and at what expected concentrations? Does it escape from the product once the solution as formalin or methylene glycol?

And, again, does it release from these formaldehyde releasers or the tosylamide formaldehyde resins into indoor air at what expected concentrations? And, finally, to what extent is formaldehyde still being used in nail products? What alternatives are currently being considered or used or evaluated?

Next is toluene. Toluene is used as a solvent in nail products for ease of application. It’s also often added as a thinner to products at the nail salons at the
time of consumer application. It’s a developmental
toxicant, a neurotoxicant, and it’s volatile with potential
human inhalation exposure.

Is toluene still used in nail products and at what
concentrations? How much thinner is added into these
products at the nail salons at the time of application? And
what ends up being a rough final toluene product
concentration? Are workers who add toluene-based solvents
at the salon being exposed to a higher dose of toluene than
anticipated? How are nail products formulated that result
in the need for a toluene-base thinner to be added at the
salon?

Next is dibutyl phthalate. And dibutyl phthalate
is used in nail polish as a plasticizer, typically in
concentrations at less than 10 percent and reduces cracking
by making the nail polish less brittle. It’s a reproductive
toxicant and a developmental toxicant with potential
endocrine disrupting action. It also has a cumulative
contribution with other phthalates in terms of their toxic
mode of action. Unlike the other two chemicals of the toxic
trio, dermal exposure is of more concern as opposed to
inhalation concern, and it’s been banned for use in
cosmetics in the European Union.

Is there any evidence that indicates human
exposure to dibutyl phthalate from nail care products? What
plasticizer alternatives are being used for dibutyl phthalate? Is triphenyl phosphate the preferred plasticizer alternative? Or are others equally effective and in use? Are there alternative assessments for nail polish plasticizers available?

And, finally, I’ve also included a slide here for triphenyl phosphate. Triphenyl phosphate is used also as a plasticizer in nail products and is a common alternative to dibutyl phthalate. It’s a potential endocrine disruptor and a potential reproductive toxicant and dermal exposure is of the most concern due to its readily absorption across the skin. What is its frequency of use in nail products and are they alternatives for triphenyl phosphate?

This table is put together based on some reporting. The toxic trio via general consensus, is being phased out of nail care products. However, according to the Environmental Working Group’s Skin Deep database and the California Department of Health Safe Cosmetics database, a number of products, nail products, have been identified to still contain these chemicals. We obviously are interested in whether these chemicals are still being used in products? What is the future trajectory for these chemicals in products? How does the future look with respect to their use and potential alternatives. I’ve also included a couple of links here to these databases for your own interest.
Here’s a list of additional Candidate Chemicals believed to be present in nail products. It was compiled from the California Department of Public Health Safe Cosmetics database as known or suspected to cause cancer, birth defects, or other reproductive harm as well as the chemicals that were identified during DTSC’s 2012 sampling study. It is not considered to be a comprehensive list of chemicals detected in nail products. It’s simply a starting point for our conversation regarding what types of chemicals may be in nail products and if they pose any potential risk or hazard or exposure potential to humans.

As a result, I’ve also included a bullet marked as “others” to capture any potential chemicals or Candidate Chemicals that may be in nail products but may not be included in this initial list. Once again, I provided some source link information.

Where is the market going, and what are the regulatory trends with respect to nail products? Recently there’s been an incredible public interest in safer products. And California has engaged in voluntary healthy nail salon programs throughout the state and through multiple counties. In addition, Walmart has asked suppliers to remove the toxic trio of chemicals from their supply chain. And Target has just initiated a new chemical strategy where they hope to have removal of phthalates and
formaldehyde from products by 2020.

In addition, there are a number of products designated as “free,” such as the 3-free, 5-free, 7-free, and 9-free nail products. These products do not reportedly contain the toxic trio and other potential Candidate Chemicals or other potential chemicals of interest. And I’ve adapted this table from Dr. Ceballos’ poster presentation on the types of chemicals that are in these nail products marketed or advertised as free. And I’m sure she’ll talk about this in more detail, but I think the real purpose here of this slide is to indicate DTSC’s interest in alternatives. What types of chemicals are being used in place of these ten here that are looking to be replaced in terms of 10-free marketing or 3-free marketing? What types of other options exist? What benefits do they offer and what obstacles exist?

In summary, DTSC is seeking input from stakeholders and moving forward on chemicals in nail products due to the hazard traits associated with the toxic trio and the awareness that there are other Candidate Chemicals in nail products, the potential exposure and adverse impacts to workers and consumers in California, especially to pregnant women and children, and the associated nail salon worker safety legislation.

Thank you so much for your attention and I’ll hand
it back to Marcia.

    MS. RUBIN:  Okay. Thank you.

    We have about 20 minutes now to take questions or
    comments on the presentations that you’ve just heard. We’ll
    start with people here in the room and then move to people
    participating remotely.

    MS. PORTER:  I really appreciated that
    presentation, Eric, and I’m wondering, are slide
    presentations going to be available? Because there were a
    lot of great slides in there that I know that we at the
    Collaborative would love to have available to us.

    MS. RUBIN:  I’m just going to repeat the question
    for the benefit of the people participating online. Her
    question was: Will the slide shows be available?

    MS. PAPAGNI:  Yes, all the slides will be posted
    on the DTSC website after the workshop.

    And, if each person could say your name and your
    organization before you state a question or comment, that
    would help us.

    MS. PORTER:  Okay.

    MS. PAPAGNI:  Especially for our court reporter.

    MS. PORTER:  If I could have a quick follow-up
    question. This is Catherine Porter with the California
    Healthy Nail Salon Collaborative.

    On the one slide with the “Xs,” the grid of the 3-
free, 4-free, 5-free, there were some squares that were
green, what did the green squares mean?

DR. SCIULLO: I didn’t go into it as much because
I have a sense that Dr. Ceballos is going to talk about it
more, but the purpose of that was to show that once you get
past 3-free and 5-free, there’s not a real standardization
in terms of what those ingredients are. So in some
products, 7-free is different from 7-free that you may see
in another product and those chemicals may swap. That’s
what the color coding was trying to show in that case.

MS. PORTER: I see. Thank you.

MS. RUBIN: Okay. In the back, please.

DR. PEREZ: I’m Angie Perez, I’m with Cardno
ChemRisk, and I just had a quick question about your
Candidate Chemicals. I know we talked about this a little
bit in the November meeting, but I noticed that, for
example, retinyl palmitate which is Vitamin A1 supplement.
I’m just curious, are you planning to pare those down a
little bit more or is this the final list?

DR. SCIULLO: No, I wouldn’t say this is final.
It’s quite the opposite; it’s just an initial starting
point. The Candidate Chemical list that I showed up there,
it was a simple, compilation of source information. We
haven’t made any informed decisions around those chemicals,
we haven’t done any paring down yet, but those kinds of
actions and decisions will be taken as we move forward, depending on the input and the research that we gather.

DR. PEREZ: Okay.

MR. ALGAZI: I’ll add something to that.

The Candidate Chemical list was -- this is André Algazi for those of you on the Web.

The Candidate Chemicals list is incorporating external lists that were generated by various authoritative bodies; some of them are governmental or international organizations. Depending on how you count them, there are several thousand chemicals included on that list. Some of them are part of groups, some of them are listed individually on one or more of the constituent lists that make it up. This list was drawn from the compiled lists of Candidate Chemicals that is posted on the website. I think Eric is just listing them to say these are things that appear on the list for whatever reason that have been detected or that we’ve had information suggesting are in or have been in nail products.

Whether or not all of these are of particular interest, we haven’t made that determination. But the Candidate Chemicals list is what it is and there are several thousand chemicals on it.

MS. RUBIN: For people listening in, her question was whether the list that Eric showed earlier in his
presentation, is the final determination.

Angie, did you have a follow-up question?

DR. PEREZ: I did.

MS. RUBIN: Okay.

DR. PEREZ: Unless somebody else has one.

I was just curious, a couple of these chemicals, like carbon black and titanium dioxide, are you going to be distinguishing in any way between nano scale and non-nano scale?

MR. ALGAZI: We haven’t made any decisions about whether or how we will focus on those chemicals or whether we’ll focus on nano versus larger, it’s really just here’s some things that we’ve found, information we found, in nail products. If we should be focused on nano scale, then that would be good information.

DR. SCIULLO: I would say that if those things end up becoming significant and on our radar for further work, then those types of issues and questions will likely arise.

MS. RUBIN: All right. For those people listening in, her question was about whether we would distinguish between nano scale and non-nano scale chemicals when it comes to the Priority Products.

I saw your hand go up on this side.

MS. MONTGOMERY: Katherine Montgomery from Coty.

You mentioned a lot about hazard, but you discuss
a lot about risk. When you’re looking from a safety assessment standpoint, you need to weigh hazard versus risk, so how is that being taken into consideration during their review of Candidate Chemicals?

MS. RUBIN: For those of you listening in online, her question was about hazard versus risk and how we take that into consideration.

MR. ALGAZI: This is Andre again. And the framework of our Safer Consumer Products regulation is not a risk assessment framework. It’s looking at the hazard and the potential for exposure and the potential for adverse impacts. We don’t have a system whereby we calculate the risk posed by an exposure and then determine whether it’s above or below some threshold, there’s not an algorithm for determining an acceptable versus unacceptable risk, that’s just a different sort of paradigm that we’re working in.

But we do definitely have those criteria that I showed my slide which there has to be potential for exposure and potential for the exposure to contribute to or cause significant or widespread adverse impacts.

It’s a more narrative approach, but if there’s no adverse impacts, then we wouldn’t choose to focus on that particular chemical-product combination.

DR. SCUILLO: And one thing to add, if there are risk assessments done on particular chemicals or products or
exposure scenarios available, obviously we’ll be considering
those as part of our evaluation.

MS. MONTGOMERY: So, for example, almost all of
your Candidate Chemicals have been safety assessed by
outside agencies.

DR. SCIULLO: Right. And those types of
assessments will be part of our evaluation.

MS. MONTGOMERY: Okay. Thank you.

MS. RUBIN: Yes.

DR. POWDER: So I have a question for Doctor --

MS. RUBIN: State your identification.

DR. POWDER: Oh, I’m sorry. Jill Powder from
Environmental Health Decisions.

I have a question for Dr. Algazi. Is that right?

MR. ALGAZI: It’s mister, but yeah.

DR. POWDER: Mister. Okay.

MR. ALGAZI: But thank you.

DR. POWDER: At least I errored in the right
direction.

You had mentioned something regarding program
guidelines for cities and counties. And I was wondering
what the logistics of that would be. Would that be
something that a CUPA would get and then they would be
responsible for implementing those programs in local nail
salons or what is that about?
MR. ALGAZI: Under this legislation, AB 2125, we’re directed to develop guidance and collaborate with Department of Public Health and somebody else and --

DR. SCIULLO: BBC and OSHA.

MR. ALGAZI: Yeah. And OSHA. Barbering and cosmetology. We’re supposed to collaborate with some other agencies, with local agencies that already have a program, so that the overarching goal is to have more standard definition of what it means to be a healthy nail salon, to have some understood standards. It’s not an enforcement-related program; it’s a program where the salons would seek recognition. I don’t think the CUPAs are directly involved in this -- implementing this legislation.

DR. POWDER: I see. So, the salons would seek recognition as part of this program and they would get some kind of a seal, so consumers could see this is a healthy salon --

MR. ALGAZI: Right.

DR. POWDER: -- is that the goal?

MR. ALGAZI: Yes, and the consumers would have some understanding of what it means when they see that because there would be some sort of criteria that have been defined.

DR. POWDER: Great.

MS. RUBIN: Did you want to -- Catherine, did you
want to add anything to it?

MS. PORTER: Yes, this is Catherine Porter with the California Healthy Nail Salon Collaborative.

The Collaborative, along with some of our county and agency partners, some of whom are here, have been developing these programs over the last five or seven years, and they’re local voluntary programs that are implemented by local entities by cities and counties or cities or counties. And they run basically like green business programs do. You have to meet certain criteria and then you’re recognized and then you can use that for marketing reasons.

Those have been in existence already and the involvement of DTSC is going to hopefully give it an extra boost and some additional sets of eyes to look at the guidelines and to help with notifying and telling consumers about these programs.

DR. POWDER: Where would one start to see if their city or county has something like this going on?

MS. PORTER: Well, there are City and County of San Francisco, San Mateo County, Santa Clara County, Alameda County, and the City of Santa Monica, those are the existing programs.

DR. POWDER: Oh, okay.

MR. ALGAZI: Part of what we will be doing is some outreach and education. Once we’ve carried out what we’re
supposed to do under this bill, there will be more information available on our website.

    DR. WILLIAMS: Over the course of the next year, you’ll start to see the information about how municipalities can get involved, but we’re just in the very early days of mapping out the plan for implementing.

    MS. RUBIN: Angie.

    DR. PEREZ: Oh, sorry.

    MS. RUBIN: It’s okay.

    DR. PEREZ: Angie Perez, Cardno ChemRisk.

    I was curious about that plan, because one of the things that I have noticed is that there’s a severe lack of any kind of consistent epidemiology data that would suggest that nail salon workers are at increased risk. Is part of this plan to also include some sort of biomonitoring or is there any kind of disease reporting pathway for these workers?

    MS. RUBIN: So her question was: Are epidemiological studies and biomonitoring being considered for our plan going forward.

    DR. WILLIAMS: This is Meredith Williams and there were no provisions for that in the law and no resources provided for being able to conduct that. I think it would be fantastic to be able to do that but we just don’t have the resources.
Catherine, am I right?

MS. PORTER: There has been one small follow-up study to the program in San Francisco, and it did show that healthy nail salons did have lower amounts of I believe toluene in the air. And there also have been biomonitoring studies of nail salon workers that do show an increased level of dibutyl phthalate via biomonitoring programs. There is already some evidence of exposure and there’s evidence of harm from those chemicals.

DR. PEREZ: Evidence from those chemicals as they relate to nail products or for those chemicals as they relate to animal studies?

MS. PORTER: There has been no, as far as I know, probably the kind of study you’re looking for. We’d love it if someone would finance a study like that. Maybe industry could help us with that.

MS. RUBIN: Okay. Do we have any more questions or comments from anyone in the room?

Okay. Via webinar?

MR. JOELSON: No questions at this time.

MR. RUBIN: Okay. In that case, we’re going to take our break a little bit early. We’ve scheduled a break until 10:15. We will start promptly with our next presentation at 10:15, so please be back in the room with enough time to get going and settle down.
MR. ALGAZI: Thanks.

MS. RUBIN: Thank you.

[Whereupon a recess was taken at 9:53 a.m.]

[Whereupon the workshop resumed at 10:16 a.m.]

MS. RUBIN: I’d like to introduce our next presenter, who’s presenting remotely. It’s Diana Ceballos. She’s a Ph.D. She’s a visiting scientist at the Harvard T.H. Chan School of Public Health. And her presentation is called, “Evaluating Product Labels and Ingredient Composition of Nail Polishes to Inform Safer Alternatives.” Please give your attention to Diana Ceballos.

DR. CEBALLOS: Hello, everyone. Can you see my screen?

MS. PAPAGNI: Not yet, Diana.

MS. RUBIN: And if you could speak up, Diana, that would help us a lot. Thanks.

DR. CEBALLOS: Can you hear me better?

MS. RUBIN: Yes.

MS. PAPAGNI: We can hear you better. We’re having a technical issue on our end, so if you could just wait one moment, we’ll let you know when your slides are up.

DR. CEBALLOS: Sure.

MS. RUBIN: Can everyone hear back there? I’m also going to take this opportunity to ask you, all of the speakers, to ask you to wait for me to
repeat any questions that you receive so that the people online can hear them. And, also, when you’re presenting, try to speak up as much as you can. And if you’re presenting from this room, please stand close to the podium so that your presentation will be heard by everyone participating remotely.

I think in just one second we’ll have your screen up, Diana.

MR. JOELSON: There we go.

MS. RUBIN: Okay, so we’re ready for you, Diana.

Thank you for your patience everybody.

DR. CEBALLOS: Good afternoon. Do you hear me okay?

MS. RUBIN: Yes.

DR. CEBALLOS: Great. Thank you for the invitation to your webinar. I would like to acknowledge my coauthors Anna Young, Joseph Allen, and Thomas Webster. And I would like to make a brief introduction of the nail salon industry and its chemical hazards, very briefly, about current studies and some preliminary results presented by Anna Young, our graduate student here, and a little bit of our future studies in mind.

As you all know, the nail salon industry has had a booming in the last decade. It is estimated that it’s a $9 billion industry and it has at least 130,000 nail salons in
the United States with 400,000 licensed nail salon technicians. And there’s a revolution of nail procedures, polishes, nail art, and brands that have been evolving, including finishes that last much longer. And getting nails done has become a staple of the youth culture. And what we commonly knew as solid colors and French manicures have even evolved into unique pieces of art on nails and a lot of different options for colors.

The industry has workers that are vulnerable for different reasons. First, they work in small businesses that often have less resources and information on health and safety. Most of the workers are female and young which makes them vulnerable for reproductive health issues. Majority are immigrants which create multicultural and multilingual workplaces that also present challenges for health and safety. Some of the workers have low education and the licenses require limited training, not always including health and safety. And they’re exposed to complex chemical mixtures.

With little control including inappropriate use of personal protective equipment, including surgical masks which are not considered respirators like in the photo, unfortunately, no gloves, even when policy has changed like in New York, and little ventilation.

As most of you know, the New York Times did a
series of articles exposing some of the hazards in the workplace at least in the New York area and they highlighted cases of women suffering reproductive health, cancer, lung disease, nosebleeds, and skin conditions. But what was most important of these articles was the acknowledgement of the little health studies that have been done for this industry.

Even though there’s been just a few studies because some of them have only approach cosmetology as a whole and there’s only a few that do manicurists. Some of the health concerns that happen most of the nail salon work included skin irritations, respiratory conditions, headache, neurological problems, and maternal complications. However, more longitudinal studies are needed that have a strong exposure of some of components to be able to understand better how to prevent these problems from happening.

Some of the chemicals that are in these workplaces include volatile organic compounds like solvent in the nail polish removers and glues. Some of them include toluene, acetone, formaldehyde that are toxic. Studies have assessed exposure to volatile organic compounds and levels are often below occupational exposure limits emitted by the strong odors often caused by the alkaline. For example, toluene mean air concentration is only 84 ppb, so they’re well beyond regulation. However county health concerns then start playing a role in these work populations.
Exposure to volatile organic compounds is informed because they can be a measure of ventilation in these salons. For example, in a study in the Boston area, it shows a level of total VOCs is associated with lower ventilation. We’ve also known that most salons are usually above the ASHRAE minimum ventilation requirements of 8600 ppm carbon dioxide.

Other chemical hazards include semivolatile organic compounds. It’s specifically plasticizers in the nail polish that include phthalates and other plasticizers like triphenyl phosphate.

And few studies have assessed these exposures. The conclusion on exposures to SVOCs from the few studies is that definitely there is a workplace component to these exposures; partly, because they’ve been clear, that air concentrations of some of the solvent measures occurred in nail salons compared to other indoor environments were higher in salon workers compared to other workers and the general population. And metabolites in urine increased throughout the work shift. However, some of the solvents are no longer added to the nail polish and this is why it’s important to have more positive data before if starting larger studies that include these exposure assessment measurements.

For the plasticizers, one concern is potential
dermal contact exposure and these have been highly neglected in the literature, but there’s enough evidence that urine metabolites in the urine decrease if workers use gloves or for example if you are self-apply nail polish when you’re using gloves, it decreases your exposure.

Another chemical concern is metal contaminants which often comes from pigments in color like in red colors and it may include some heavy metals that are also concerns with reproductive and other health hazards. But there’s definitely an increase in metallic and shimmer finishes that could be increasing the levels of metal contaminants. Since that has not been looked at, this is one of the key questions that we’re asking in our studies.

In general, our studies are trying to understand the exposures of chemicals that may affect reproductive health, including VOCs, SVOCs, and metal contaminants, understand how these metal chemicals get into our bodies, both through inhalation and dermal absorption, and understand sources of these chemicals. And today we’re going to present some preliminary data on understanding sources of the chemicals.

MS. YOUNG: In our conversations with nail salon workers, we’ve learned that they state confusion about the chemical ingredients in nail polish and how to choose safe brands. We wanted to research the full ingredient
compositions of various nail polishes as well as their product labels to better understand the chemicals that workers and consumers are exposed to.

We identified 20 commonly used nail polish brands based on market statistics and visits to nail salons in Boston. For each brand, we located Safety Data Sheets which are chemical hazard information sheets required in nail salons by the Occupational Safety and Health Administration. We found that few salons listed these data sheets. Although some manufacturers voluntarily provide a complete list of ingredients, most only disclosed a handful of ingredients that comprise more than one percent of the product, or more than 0.1 percent.

A handful of the SDSs we looked at did not disclose some ingredients in the composition section because there are trade secret claims, as you can see in this example on the bottom left. However, trade secrets have to be well supported since they are not specifically claimed.

Finally, the SDSs were very difficult to track down and frequently required us to contact manufacturers directly. These three challenges can significantly limit nail salon workers’ access to chemical hazard information.

We also tracked down consumer product ingredient lists which are required by FDA for products marketed on a retail basis to consumers, but not for products
professionally used in nail salons. These ingredient labels often provide much more comprehensive information. The label on the bottom right lists the same product as the SDS example but lists many more chemicals, demonstrating where SDSs lack.

In our research of 20 brands, we found over 200 unique ingredients in nail polishes which make safety evaluations difficult. There are also a couple of limitations to these lists. Companies can list colorants without providing specifics and can also list fragrance as an ingredient, their trade secret concern. The plasticizer dibutyl phthalate is one such ingredient that can qualify as fragrance.

The good news is that companies have been proactive about removing certain ingredients of concern. We’ve seen many 3-free nail polish products emerge in the last decade which are free of the toxic trio dibutyl phthalate, toluene, and formaldehyde. As more ingredients are found to have toxicity concerns, some companies have transitioned to 5-free and even up to 10-free.

Because of the wide variety of product labels and confusion about their definitions, we put together this table. On the top are the product labels, from 3-free to 10-free. On the left are nail polish ingredients. And then “X” indicates that the label reports the product to exclude
that ingredient. You can visually see how the labels have evolved over time, continually removing more ingredients. 3-free removes the toxic trio, 4-free also removes cancer, 5-free removes formaldehyde resin.

As new labels have emerged more rapidly, the label definitions become less clear. The 7-free and 9-free labels are defined differently by some companies. The 6-free nail polish has excluded nitrocellulose but none of the later labels do. And although all exclude dibutyl phthalate, only two labels exclude phthalates in general.

Some labels also address other types of ingredients such as trace amount contaminations, fragrances, and animal ingredients. These labels are important steps to reducing nail polish toxicity, but they are not consistently defined and the implications of each label for health are not listed, making decisions by nail salon owners, workers, and consumers difficult. Advertisements about “safe”, “non-toxic”, or “natural” nail polish can also potentially provide false reassurances.

One concern about evolving labels that will be important to address is regrettable substitution of ingredients. Although none of our research products disclose dibutyl phthalate, one of the toxic trio, 13 of the 20 disclose triphenyl phosphate, an alternative plasticizer. Although there’s limited data about TPHP, it has been linked
to endocrine disruption, reproductive and developmental
concerns, and skin sensitization. A few brands are now
reporting to be free of TPHP, as you may have seen in the
table, so we need to work to ensure the ingredient
substitutes are safe.

Another challenge with labels is quality. The
Department of Toxic Substances Control tested nail polishes
and found out the majority of 3-free or toluene-free nail
polishes did contain one of those ingredients, and often
even in higher concentrations. For example, in our table
here, you can see that median dibutyl phthalate
concentrations are higher for those with 3-free claims
compared to those without. For example, 76,000 ppm for 3-
free polishes compared to 24,000 ppm. And similarly for
toluene.

We are currently conducting a couple of pilot
projects to determine exposure by nail salon worker space.
We are analyzing nail polish samples for plasticizers and
heavy metals which we will compare with SDS and label
information. We are also measuring solvents exposures
through blood, breath, and air samples. Plasticizer
exposures through urine, skin wipes, and air samples. And
heavy metals exposure through toenail samples and surface
wipes.

We hope these pilot projects inform future studies
to assess the effectiveness of intervention to nail salons
to health effects of exposures in the importance of workers,
training, and outreach. We look forward to continued
efforts by industry, government, academia, and advocacy
groups to build on current progress on approving the
chemical safety of nail products.

Thank you. We’d like to acknowledge our sources
of funding and support. And we’ll have time for questions.

MS. RUBIN: We’ll take questions from anyone in
the room. Again, please let me repeat the question before
you answer it. Sir.

MR. SCHOON: Yes. My name’s Doug Schoon with the
Professional Beauty Association. I may have misunderstood
but it seemed like the insinuation was because a Safety Data
Sheet doesn’t contain all the ingredients on the ingredient
label, that Safety Data Sheet was missing information. And
I just want to make it clear that the Safety Data Sheet
doesn’t always contain all of the ingredients on the label.
Water would be a good example of what you won’t necessarily
see on the Safety Data Sheet even though it would be on an
ingredient list.

MS. RUBIN: Okay. So his comment -- it was a
comment?

MR. SCHOON: It’s more of a comment.

MS. RUBIN: Okay. His comment was about the Safety
Data Sheet may not necessarily contain all of the data that is on the label.

MR. SCHOON: And it would still be correct.

MS. RUBIN: But it would still be accurate.

DR. CEBALLOS: Correct.

MS. RUBIN: Okay.

DR. CEBALLOS: Yeah.

MS. RUBIN: Thank you.

DR. CEBALLOS: We agree. Thank you for the comment.

MR. SCHOON: I thought I just misunderstood.

MS. RUBIN: Okay. And it was also clarification. Thank you.

All right. Yes?

Oh, also, can I make a note. If you’re sitting in this U-shape area, it’s hit or miss with whether people can hear you or not, so please speak up. Thank you.

DR. POWDER: Jill Powder with Environmental Health Decisions. You were talking about some pilot studies being done with regard to exposure. Who are those pilot studies being done on and how are you getting volunteers or people to be a part of those pilot studies?

MS. RUBIN: Jill’s question is about pilot studies and the details of them. Where do the people come from that participate in the pilot studies. And -- is that it?
DR. POWDER: That’s pretty much it.

MS. RUBIN: That’s pretty much it. Okay. Thanks.

DR. CEBALLOS: Hi, this is Diana. We have three ongoing pilot studies that are basically funding this, you know, a main study. And we basically have ten nail salon workers from the Boston area and we’re just recruiting volunteers through our network. And we’re working with the Massachusetts Healthy Cosmetology Committee, a stakeholder group in this area to sort of help us promote this study. Anna is doing more work and specifically with metals so that may end up recruiting another ten. They are workers, so we go to their nail salon for one day.

MS. RUBIN: Okay. I believe Karl has a comment or question.

MR. PALMER: Yes. Thank you for your presentation. This is Karl Palmer from DTSC. My question is on the table that shows the various 3-, 5-, 7-, 9-, 10-free categories, my assumption is that all of those chemicals serve some functional use in the product. So my question is, have you gone the next step to create a table which then sort of fills in comparing ingredients from these products of what you assume might be the specific chemicals which take the place of those constituents which are not there? This is to get to the question of, well, if you’re not using something, maybe
that’s great, but what are you using instead for that same function and do we have any assessment of those hazard traits and potential challenges?

MS. RUBIN: Karl’s question was about the product label table that Diana showed, and if there has been further research determining what the substitutions for these chemicals might be.

MS. YOUNG: Hi, this is Anna here. So we’ve been putting together a database of the 20 nail polishes we researched, it includes all the ingredients that are in each of those products, and our research products include some of the new safer alternatives. We’re trying to identify some substitute plasticizers and other ingredients.

We’ve identified some plasticizers that seem to be growing in popularity such as acetyl tributyl citrate and some others, but we don’t have complete information on that right now. But that’s a great point. Thank you.

MS. RUBIN: Yes.

MS. GRESS: This is Ky Gress from the Safer Consumer Products Program. I was just curious if you’re looking at any products that are specifically marketed to children.

MS. RUBIN: Ky’s question was if you are looking for any products specifically related to children.

MS. YOUNG: There are a couple of products. We’ve
seen some labels saying safe for children or safe for pregnant women. Although we haven’t found those to be common, it is important to evaluate the implications of those labels and what they mean for health.

MS. RUBIN: Thanks. Yes.

MS. BALKISSOON: Indira Balkissoon of AlterEcho. I have a question about NMP. Are you seeing anything in the nail polish removers, has that been showing up at all?

MS. RUBIN: Her question was about NMP, and if it’s been found in nail polish removers or elsewhere.

DR. CEBALLOS: Right now we have focused on the preliminary data, and what we were showing is exclusive for nail polish and we haven’t looked at removers. But actually every time we’ve been to the nail salons which we visited, six by now, they actually use pure acetone, almost exclusively. Originally I was going to be more focused on analysis of commercial removers, but my work is really with the workers. So far, it’s not really a need and it may be more for a project that focuses on consumers. But I’ll just have to finish the rest of my nail salon visits to make that determination.

MS. RUBIN: Okay. Thank you.

Any other questions or comments in the room?

Yes.
MR. JOELSON: We have a question from the web.

MS. RUBIN: Oh. Okay.

MR. JOELSON: Mr. David Lennett asks, what is the timeframe for completing the exposure studies, particularly for the solvents exposures study?

MS. RUBIN: His question is about the timeframe for completion of the solvent exposure study.

DR. CEBALLOS: Our ideal date is in April but with another conflict in scheduling, it may be more like May. But thankfully with solvent data usually we see the data much quicker. I’m really hoping that that would move much smoother in terms of publication and future grants.

The plasticizers lab analysis are more complex and laboratories usually take much longer than that. Even if we finish in the field soon, it would likely be more like next year by the time we have things done.

MS. RUBIN: Great. Thank you.

Any other questions from our remote participants?

MR. JOELSON: No more questions.

MR. RUBIN: Okay. Anyone else in the room have a question or comment?

Okay. Thank you so much.

We’re going to move to our next presenter, Alexandra Scranton. She is also participating remotely.

She’s the Director of Science and Research for Women’s
Voices for the Earth. And her presentation is, “The Potential Hazards of Undisclosed Fragrance Chemical Exposure in Nail Salons.”

So we’ll be moving the presentation control over to her in just a minute.

Alexandra, are you on the line?

MS. SCRANTON: Yes.

MS. RUBIN: Okay.

MS. SCRANTON: Can you hear me?

MS. RUBIN: Yes, we can hear you. Just give me a second to make sure that your presentation is cued up, okay?

MS. SCRANTON: Sure.

MS. RUBIN: Okay. We’re ready to go. Thank you so much.

MS. SCRANTON: Okay. Terrific. Thank you so much for letting me present. Again, I’m Alexandra Scranton, Director of Science and Research for Women’s Voices for the Earth.

For those of you who may be unfamiliar with my organization, we are a women’s environmental health advocacy organization that works to amplify women’s voices to eliminate toxic chemicals that impact our health and community.

We’ve been researching and working on the issues of hazards to nail salon workers for over a decade and been
particularly focused on hazards of fragrance for the last several years. My presentation is on fragrance in nail salons.

The first obvious question is: where are we seeing fragrance in a nail salon? I think traditionally when we think of hazards in a nail salon, we think of products like nail polishes, top coats, acrylic nails, polish removers, solvents, that kind of thing. These products while occasionally are scented, novelty nail polish that smells like strawberries, most of these are not scented. Where you’re finding fragrances is in the pre-manicure and pre-pedicure application. It’s the lotion that gets rubbed on your hands or on your feet. It’s the massage oils that get used when you’re soaking your feet or your nails. Those products have fragrance in them. They’re often advertised as kind of aromatherapy, these products are technically applied to your feet or your hands but it scents the whole room and adds to this kind of spa experience.

These are the products that are used virtually on every client that a nail salon worker works on so these exposures are repeated numerous times per day, regardless of the other service a customer is getting. And of course, as has been discussed by other speakers, this work is predominantly done without gloves, so there is significant exposure to the nail salon worker.
In addition, because there are so many other odorous products associated with nail salon work, air fresheners are commonly used throughout beauty salons in effort to mask the odors of other products like acetone. The fragrance is pumped into the air in salons. Similarly, cleanliness and sanitation are real priorities and certainly requirements in nail salons. The vast majority of cleaning products and disinfectants used in salons are going to have the light scent of something to try to make them more pleasurable. These are also ongoing exposures throughout the day as well.

Now when we talk about chemical exposures from fragrance, keep in mind that fragrance doesn’t have to be one simple chemical composition. Any one fragrance can be made up of over a hundred individual fragrance chemicals. And, unfortunately, due to long history of tradition in the fragrance industry, these ingredients are generally not disclosed.

Decades ago when this was first written into laws, and as you see here where ingredients are required to be disclosed, fragrance was allowed to be disclosed simply as the word fragrance. And this tradition of a special nondisclosure status for the fragrance industry has continued unfortunately well past its usefulness, and I’ll talk a little bit about that later.
While we’re hampered by this kind of lack of disclosure, we don’t have specific information about what’s in an individual fragrance. What we do know about fragrance comes largely from a list of ingredients voluntarily disclosed by the International Fragrance Association, IFRA, on their website, it contains just under 3,000 ingredients currently used in fragrance. And I’ll call this list, the IFRA list.

And from this list we can really learn something about potential hazards that may be present in fragrance. Specifically, when we look at the list, and perhaps most relevant to the DTSC, there are 54 fragrance chemicals I was able to identify on the IFRA list that are also on the California Candidate Chemicals list. These are chemicals of interest to the DTSC, for honestly a number of reasons. Any of these 54 chemicals could be present and undisclosed in any fragrance product; we just don’t know which product or which chemical.

I decided not to create a slide for you with the full list of 54 Candidate Chemical names, too hard to read, but that full list is available on our website link below.

A few of the highlights of the kind of ingredients you can find in fragrance, which are things like styrene, parabens, pyridine, cresols, xylenes, phthalates, nonylphenol, etc., 30 or 40 other chemicals. It's a
significant list of chemicals with a host of potential hazards including cancer and endocrine disruption, environmental effects and more.

To give you another idea of the kind of chemicals that can be present in fragrance, we also did an analysis looking at the Globally Harmonized System, the GHS classification for fragrance chemicals. These are kind of the indications of how chemicals should be flagged or classified on their Safety Data Sheets.

There are 190 fragrance chemicals that have been assigned the signal word danger. Due to their characteristics, over a third of fragrance chemicals have been assigned the word warning. There are 44 that need a skull and cross bones for acute toxicity, 97 require the pictogram for being a hazard to human health.

This gives you some idea of the extent of potential hazard in fragrances. These are the kind of chemicals that we generally want to be aware of, they’re on SDS sheets and we want to be aware of our exposure to them.

If you would like to see the list of these, you know, chemicals, they’re also available on our website, it’s that similar link from before, womensvoices.org/fragrance-ingredients. You can get all the lists and about ten others will be cross-referenced the IFRA list with various other lists, authoritative lists of chemicals and concerns.
Given that there are a number of potentially harmful chemicals in fragrance, it begs the question of what harm those fragrance exposures cause. The literature is somewhat limited, but there certainly is some. And there are studies documenting harm to human health from fragrance. By far, the most comprehensive data comes from the dermatology literature. This has established about 2 to 11 percent of the general population has skin allergies to fragrance. This translates to tens of millions of people globally. Other well-documented effects of fragrance exposure include eye, nose, and throat irritation. There are quite a few studies on fragrance-induced headaches, particularly migraines, in the literature. Fragrance exposure can exacerbate respiratory disease such as asthma and COPD. There are studies on longer term chronic effects, cancers, reproductive effects. The research has never been done looking at fragrance exposures.

There are some lists of well-documented case studies on symptoms like immune system effects, neurological effects, and certainly anaphylaxis happens on occasion. And through all of this data, a very common thread is that women are significantly more affected than men to exposures to fragrance. This is best documented in the dermatology literature; the ratio is about three to one women to men who had skin allergies as to fragrance. Given that the nail
salon worker population, and certainly their clientele, are predominantly women is a distinctive very relevant factor.

Now what do we know about the impacts of fragrance exposure to nail salon workers? I’d love to tell you there are studies on this. I could find exactly none that have looked at nail salon workers’ exposures to fragrance. I don't think there are very many, if there are any, fragrance-free nail salons that could be controlled for a study like this.

What we can, however, learn from is the epidemiological data that’s out there of salon workers that does exist. And that gives us a better idea of the conditions that disproportionally effect nail salon workers, and so this is undefined a number of conditions that affect nail salon workers. All the citations for these claims, they’re all in a report called “Beauty and its Beast” which is on our website, at that link where you can find the descriptions of the studies and the links there.

The conditions that nail salon workers are facing at higher rates officially than other occupational groups, things like skin conditions and irritations and rashes, occupational asthma to nasal throat irritation symptoms. There have been a few studies measuring decreased lung function in nail salon workers over the course of the day, increased risk of miscarriage and low birth weight babies,
headaches, dizziness, neurological symptoms. And then there were two studies particularly on immune disorders such as lupus and primary biliary cirrhosis which were significantly higher in nail salon workers.

In most cases, the researchers of these studies were unable to draw conclusions about specific chemical exposures in these conditions, but in most studies the researchers did hypothesize the chemical exposures in the salon were contributing major contributing factors.

From this information, we know that these effects are caused by fragrance exposure, however I can’t rule it out, it’s certainly a possibility of to say a contributing factor. In any case, this is important and relevant information to our discussions today. And certainly poses a valid cause for concern about the impacts of fragrance and the need for more investigation.

What do we need to know about fragrance in nail salon products in order to move forward and better protect the health of nail salon workers and their clients? Quite simply, we need disclosure of fragrance ingredients so that we actually know what we’re dealing with. I think the State of California especially should be asking for disclosure of any fragrance ingredients that are on that Candidate Chemicals list. We need to know how commonly these chemicals are used in fragrance in what kinds of product.
Ideally, we would like to see product-specific disclosure of fragrance ingredients. And, I know this sounds like a big challenge for some manufacturers who aren’t used to it, there’s potential interim step that’s not as good, asking for fragrance palates, this is just a master list of chemicals a particular manufacturer uses in their fragrance. It’s not nearly as helpful. It can identify problem products but potentially could rule out Candidate Chemicals from further investigation.

And one major reason that asking for this kind of disclosure appears to be a challenge is what I mentioned before, this long tradition of granting the fragrance industry special nondisclosure status. And this was originally instated over a half century ago into law. And, at the time, it really made a lot of sense. Fragrance formulas were very, very top secret stuff. Giving away a list of ingredients would make it a lot easier to pirate a fragrance or create a counter threat. But you fast forward to today’s technology and recreating a fragrance from a simple laundry list of chemicals is by far the hardest and most labor intensive way to try and steal a formula.

Today with gas chromatography-mass spectrometry, they really changed the game entirely. You can now plug a sample of your fragrance into your GC-MS, have it loaded with the fragrance GC-MS database, which is available from
several vendors, and you have your fragrance formula names
of specific chemicals and the percentages on a printout I
mean practically in real time. This is how counterfeiting
is done today.

I think it’s really worth being very clear here
that a simple list of fragrance ingredients really no longer
meets the definition of trade secret. I’ve got the
definition here from the Uniform Trade Secrets Act;
paraphrasing, but it’s basically trade secrets are
information that derives economic value from not being
generally known or readily ascertainable through appropriate
means by other persons who might obtain economic value.

In this case, fragrance ingredients are clearly
readily ascertainable through appropriate means like GS-MS
by competitors when they are seeking this information for
nefarious purposes.

In a report on trade secrets in the fragrance
industry written by the National Fragrance Association, it
does clearly admit that the relatively cheap availability
and analytical technologies like gas chromatography-mass
spectrometry now allow for very detailed analysis of
fragrance. Using these latest techniques to support an
experienced perfumer, a competitor can rapidly bring close
approximations of the original to the market without having
to cover substantial R&D investment of the innovator.
These compositions of these fragrances are not secrets anymore, they are certainly vulnerable. Having said that, I strongly recommend the report in the link there. There’s a lot of influential property that still exists in the fragrance industry from having ingredients extracted, how you combine those. There’s all kinds of interesting chemistry that’s going on that is certainly top secret and really worth holding on to as trade secret. But compositions of fragrances, the list of ingredients, they’re just not secrets anymore.

And I do understand that this is a really hard habit to break. There are so many laws where the fragrance exception exists. I think industry first and regulators and even activists are just used to giving fragrance industry a pass on this kind of disclosure, for so-called trade secrets reason, but we really have to get past this outdated way of thinking. It’s unfortunately keeping us in the dark from potential harms from fragrance, and it’s really preventing efforts to improve public health from these exposures.

The other issue I’d like to address briefly is this kind of rationale for backing the lack of disclosure which is this idea that fragrance and its safety is very well documented in the research. The reality is, there’s no kind of external moderating of safety assessment of fragrance ingredients. The safety of fragrance ingredients
are almost exclusively conducted by internal mechanisms
within the fragrance industry itself. There is an inherent
conflict of interest when an industry self-regulates for
safety.

This slide just briefly describes the basic
outline of the fragrance industry safety program. It does
involve publishing peer reviewed safety assessments of
fragrance ingredients. These are based on validation and
review and evaluation by an independent expert panel. They
have made a database of these studies that are used to draw
these conclusions.

And then IFRA does issue standards that determine
allowable levels of fragrance ingredients to be used in
products for fragrance ingredients that could pose harm.
And, currently, there are roughly about 200 chemicals that
IFRA has issued standards for restricting or banning their
use.

And this sounds great; there’s a lot of good
things to this program. The problem is that the safety
program isn’t actually comprehensive for all fragrance
ingredients. I was taking a look through the 54 fragrance
ingredients on the Candidate Chemicals list of those, just
three are restricted in use by IFRA. So the vast majority,
styrene, phthalates, nonylphenol, etc., can all be used in
fragrance in unrestricted concentrations.
And that’s really a concern. There is also a lack of these cumulative safety assessments of certain chemicals. A lot of these have been done, they’ve been published, you can find them in the literature, but they haven’t been done for all fragrance ingredients. There’s no easy compilation of all the safety assessments. None of the 54 fragrance chemicals on the Candidate Chemicals list has been reviewed by fragrance industry at least anytime recently that I’ve been able to find. I’ve never been able to find safety review of styrene. There are no published reviews of phthalates by the fragrance industry. There are a lot of holes in the safety program, particularly respect the certain chemicals of concern.

And if you want more information about this, we have another report on our website called “Unpacking the Fragrance Industry” which is kind of a critical analysis of the industry safety program.

To summarize, we understand that fragrance is commonly found in nail salon products in pre-manicure, pre-pedicure products. The nail salon is certainly a heavily fragranced workplace to work in. Fragrance exposure to nail salon workers is associated with virtually every client regardless of the sort of that’s requested. Fragrance exposure has been documented to harm human health. There are certainly chemicals of concern, including 54 chemicals
on the Candidate Chemicals list. And the lack of disclosure
of fragrance ingredients has really hampered our ability to
investigate these hazards and really to investigate these
exposures to specific fragrance ingredients.

In conclusion, fragrances really can pose
potential hazards to nail salon workers, and we believe it
deserves greater scrutiny and attention.

Thank you very much.

MS. RUBIN: All right. Thank you.

We’ll take questions from our participants in the
room first, or comments. Anybody?

Yes.

MS. BALKISSOON: Mine may be negative, but the
annex --

DR. WILLIAMS: Could you identify yourself again.

MS. BALKISSOON: I’m Indira Balkissoon from
AlterEcho and I work on EU cosmetic assessments. And in the
European Union, there’s 26 allergens, fragrance allergens
that are required to be labeled. So I don’t know if I agree
with that statement that they’re not included on the labels.

MS. RUBIN: Okay. So her --

MS. BALKISSOON: I don’t know if that’s a comment
or a question.

MS. RUBIN: Okay. Her comment was that there are
26 --

MS. RUBIN: -- fragrance allergens listed on EU --

MS. BALKISSOON: Pardon?

MS. RUBIN: Listed on EU labels?

MS. BALKISSOON: Yeah, the EU required --

MS. RUBIN: So theirs required.

MS. BALKISSOON: -- (indiscernible) is required to be listed on the label.

MS. RUBIN: In EU, 26 fragrance allergens required to be listed on labels.

MS. BALKISSOON: By the EU.

MS. RUBIN: But not in the United States.

MS. BALKISSOON: Well --

UNKNOWN SPEAKER: Most labels are globally compliant so they would include the EU allergens.

MS. RUBIN: So another follow-up comment to that was that most labels in the United States are globally compliant and they would include that list of the 26 allergens.

Yes.

MR. SCHOON: Doug Schoon, Professional Beauty Association.

MS. RUBIN: One second, Doug.

Did you want to respond to that at all?

MS. SCRANTON: Sure. All of the 26 EU fragrance
allergens which is a great thing for the EU customers. You do sometimes see those EU allergens here in the U.S. There are certain companies, globally, who require that. I wouldn’t say it’s the norm yet in the U.S. We have a lot of products out there that would just say fragrance and won’t have any of the allergens listed. But some do.

MS. RUBIN: Okay.

MR. SCHOON: Doug Schoon, Professional Beauty Association.

Another concern or comment I’ll make is that another thing that has to be considered is that many of these fragrances are complex mixtures of tiny amounts of 50 or 60 different ingredients sometimes. To be able to put 50 or 60 difference ingredients onto an ingredient label is a huge challenge for probably any manufacturer.

MS. RUBIN: His comment was about the number of ingredients that may have to be disclosed on an ingredient label. As you mentioned before, some of the fragrances are composed of numerous different chemicals and there could be over 50 that might have to be listed. So that would pose a challenge.

MS. SCRANTON: Sure. We certainly look at that there are a lot of way around this or, people looking at whether or not fragrances could be just found online where of course there’s unlimited space for disclosing
It’s to some degree a label design challenge. In Canada, for example, every label for consumer product is in both English and French. Every label in Canada has twice as much text as it does it the U.S. And they figured out how to do that. Given, those kind of dynamics, and certainly in Europe there’s multiple languages often on the same label. When it comes to that, there’s only room to add in the most of the ingredients that are necessary.

MS. RUBIN: Yes.

MS. MONTGOMERY: This is Katherine Montgomery from COTY.

You showed several SDSs regarding fragrance ingredients that would have the exploding chest symbol or hazard symbol. That’s for fragrance at 100 percent. And for nail polishes, or body lotions for that matter, fragrances are very rarely used above five percent so if you’re going to look at an SDS and determine hazard by that, you have to put it as a grain of salt; it’s not used at a hundred percent. If you were to pick up an SDS for an alcohol, it would have the exact same hazards on them. I mean, we all have alcohol in our houses, we use it on daily uses, it’s not really considered a dangerous material. You really need to think about what the actual exposure to the consumer is when looking at an SDS.
MS. RUBIN: Her comment was about the slide that you had with the SDS label and the levels of exposure people would have to any of the fragrances or chemicals. The exposure is a hundred percent for it to be dangerous and rarely are these chemicals used at that level in nail polish or lotion; they’re usually closer to five percent. Did I capture that accurately?

MS. MONTGOMERY: Yes.

MR. RUBIN: Okay.

MS. SCRANTON: Yeah, thank you. That’s a really good point and a really good comment.

I think what we have seen particularly with the new SDSs that have come out for the latest hazard communication standard is that we have seen some examples of products that are now starting to disclose some of those fragrance ingredients that have never been disclosed before, particularly chemicals that are carcinogens or the ones where there’s so much lower thresholds for reporting on an SDS. We are starting to see some of that -- some of that disclosure come around.

It’s certainly not standard. I think companies are still getting used to having to do the SDSs; they’re very much not used to disclosing fragrances. But there are companies who look at their formulas and are like, okay, we’re over the thresholds, we need to be, we need to be
disclosing this.

   We think often of fragrance that well, one just
smells nice, it must be harmless. There can be some rather
serious chemicals that are in there. And we certainly know
very low level of fragrance can really affect a person a
great deal. There are biological effects that can happen at
very low concentrations, seen all the time in the
literature. Even a low concentration can have an effect.

MS. RUBIN: We’re going to -- you had a question,
right? You raised your hand earlier. So we’re going to --

MS. KOPELOVICH: Luda Kopelovich, Cardno ChemRisk.

MS. RUBIN: Okay. I’m sorry, could you speak up.

MS. KOPELOVICH: Luda Kopelovich, Cardno ChemRisk.

MS. RUBIN: Luda Kopelovich. And then we’ll go
over to you.

MS. KOPELOVICH: My question was a lot of these
fragrances are very commonly found in a lot of other
consumer products not just nail polish. So when you’re
looking at health risks to nail salon workers, I’m curious
to see how you are going to pick in terms of the hazard
coming from nail products versus fragrances that are
probably found in other consumer products; they’re also used
by other people, maybe outside of work.

MS. RUBIN: Her comment -- is this a question for
DTSC or for our presenter?
MS. KOPELOVICH: To the presenter.

MS. RUBIN: Presenter? Okay.

Her comment was that a lot of these fragrances might be found in other products that the nail salon workers use outside of the salon. How would we determine their use of these products outside of their work environment and their personal environment?

Is that accurate?

MS. KOPELOVICH: Sure.

MS. RUBIN: Okay.

MS. SCRANTON. I think that’s a really good point. If you’re measuring levels of these chemicals in the air, then they certainly could be volatilizing off of a person who is wearing a fragrance. If we get disclosure of what chemicals are in the products we’re actually using rather than doing it from air testing, then that will tell us what additional exposures they, in fact, have in addition to whatever they’re exposing themselves to if they choose to be someone who wears fragrance.

I think it’s just more information, it would be very difficult from air testing to be able to distinguish the two, but if we had information from the manufacturer, we would certainly be able to tell what comes from the products that they’re using every day.

MS. RUBIN: Does that answer your question?
MS. KOPELOVICH: Kind of.

MS. RUBIN: Did you --

DR. PEREZ: I mean, Luda read my mind. This is Angie Perez from Cardno ChemRisk.

Luda read my mind, had a similar question about how exactly is this specific to the nail industry? If I plug in an air freshener in my house and it’s my choice to use sprays or whatever, I mean it’s everywhere. It’s just a little unclear a why the nail salon worker cohort is the focus.

MS. RUBIN: Her question was a follow-up to the previous question. Why would the nail salon workers be of particular interest when it comes to the fragrances? For example, air fresheners. What would the difference be if one person plugged one in an air freshener at their house that periodically emits fragrance as opposed to exposure to a nail salon worker?

MS. SCANTON: Sure. Another really good question. I think there is really data the speaker before me talked about the ASHRAE standards for ventilation in nail salons. And from that particular study, I think it was in Boston that showed that the vast majority of nail salons do not have adequate ventilation based on the levels of CO2 in the air. An air freshener added to that sort of environment where there isn’t good ventilation, where there are already
high levels of the VOCs in the air, could make a bigger
difference than what’s in your house if you’ve got windows
open and you are coming and going and that kind of thing.

   It’s true, the air freshener is –not adding any
more harm in a nail salon that it is in your house. I think
there’s also problems with air fresheners in homes but it’s
the concentration overall. Fragrance is coming from so many
different potential places in a nail salon that it certainly
seems deserving of greater investigation as to what the
exposures are to the people who work there.

   MR. ALGAZI: Well, I think Angie’s point might
have been about given the ubiquity of fragrance, chemicals
in all kinds of products, why focus on nail products.
   Is that it? Yeah.

   MS. SCRANTON: Oh, sure. And I think, again, it’s
coming back to the nail salon and certainly this is true of
hair salons as well, but actually we’re talking about nail
salons today, it is a heavily fragranced workplace. I mean,
that there’s greater concentration than you might find in
your average office setting. Where there can be air
fresheners and our concern with people wearing fragrances,
but these are women applying fragrance lotion to their hands
and the hands of their clients eight, ten times a day. All
right. There’s a tremendous fragrance exposure to nail
salon workers given the work they do and the products that
they’re using.

    DR. PEREZ: One may argue, though, that you’ve
also have a significantly higher rate of hand washing which
has been shown to clear products on their hands, too. So I
I’d like to see data for that.

    MS. RUBIN: And so Angie mentioned that also in
these environments, there is a higher rate of hand washing
by the workers and she would like to see data for your
conclusions.

    MS. SCANTON: Oh, okay. I’m certainly happy to
provide that. With hand washing, a lot of soap is
fragranced too. There’s, exposure there as well.

    The point of my presentation is that there’s a lot
that we don’t know about what’s in fragrance, but there are
a number of chemicals we’re really concerned about that
could be in fragrance that these women are being exposed to,
and I think we need more information. And we need more
investigation to see if fragrances are, in fact, causing
these health effects that we’re seeing in these workers.

    MS. RUBIN: We have another question on this side
of the room and then we’ll come back over here.

    MS. LITTLE: Thank you.

    This is Susan Little with the Environmental
Working Group.

    And I just had a question in line with concerns
about the lack of data, and whether or not the manufacturers
of the products have been able to demonstrate that in that
kind of a work setting that their products are actually safe
to workers.

MS. RUBIN: Her question was about worker safety
and manufacturers being able to --

MS. LITTLE: Demonstrate --

MS. RUBIN: -- to demonstrate --

MS. LITTLE: Yeah.

MS. RUBIN: -- the safety of their products in
that setting with the lack of availability of data.

MS. LITTLE: If there are any studies to that
effect or if the industry, the nail salons, have been able
to demonstrate that the fragrances in their workplace do not
harm their workers?

MS. RUBIN: Did you get that?

MS. SCRANTON: I did, yes.

MS. RUBIN: Okay.

MS. SCRANTON: Thank you. And, thank you, Susan,

for the question.

I have not seen any studies looking at the safety
of fragrance or fragrance products in the nail salon. That
specific angle of research just hasn’t been done as far as
I’m concerned. I think there are likely research that
manufacturers have done looking at things like skin
irritation from lotions. I think they do that all the time and make sure that their customers are not immediately going to break out in a rash, or like most of them aren’t. But I don’t know, I’ve never seen studies by those manufacturers looking specifically at the occupational setting and the multiple, multiple use of these chemicals. I’d love to see it among that research; I don’t think it’s published if it’s done internally. But it’s not something I’ve been able to find.

MS. RUBIN: We only have time for one more comment and we’re going to take it from -

MS. PORTER: Catherine Porter with the California Healthy Nail Salon Collaborative.

Just a quick comment about what a nail salon worker’s exposed to at work and what she may be exposed to elsewhere. I think there may be a host of chemicals that nail salon workers are exposed to both at work and at home. I will be talking about some of those chemicals.

But I don’t think that should be reason for those chemicals not to be targeted in the nail salon working environment. If we can start whittling away at some of the exposures of any worker, any individual, I think it behooves an agency to do that.

MS. RUBIN: Did everyone get that? Alexandra?

MS. SCRANTON: Thanks, Catherine.
MS. RUBIN: Okay.

MS. SCRANTON: Thanks, Catherine, that was a great point.

MS. RUBIN: Thank you for your presentation.

We’re going to move on to our next presenter who is here with us.

We have Katherine Montgomery, the Senior Director for Corporate Regulatory Affairs with Coty, Inc. And let me just get her presentation set up for you. It is, “An Industry Leader’s Perspective on the Regulation of Nail Products and their Ingredients.”

MS. MONTGOMERY: Good morning, good afternoon, for everyone that’s on the phone that’s not on the West Coast. My name is Katherine Montgomery, I’m from Coty. And I wanted to first start by thanking DTSC’s Safer Consumer Products Program for inviting me to speak to you guys on the industry’s behalf or from an industry’s perspective.

We’ll go from a little bit more general to more specific on all nail products from what’s in the nail products to the chemicals, how they’re manufactured, and of course the focus on safety. In order to frame exactly what I’m going to go over, I wanted to give you a background on exactly who Coty is. We currently don’t manufacture anything under our actual name. But I wanted to give you an idea that we have over 70 brands ranging in luxury
fragrances, color cosmetics, professional hair color, and luxury skin care. We’re sold in 130 plus countries. We have over 20,000 employees, and we have roughly $9 billion in revenue.

As a little bit more exciting way of looking at it, these are some ideas of our brands. You’ll see listed OPI Nail – OPI, Incorporated and also Sally Hansen which are two of the major nail product companies out there in the U.S. You’ll also see a lot of our fragrances like Bottega Veneta, Miu Miu, Marc Jacobs, and some of our color cosmetics such as Cover Girl and Rimmel.

Given that we’re talking specifically about nail products, I wanted to give you some background on OPI Products which is located here in California, in Southern California and North Hollywood. They sell primarily to distributors who sell to salons so they do professional nail products. They are members of several industry trade associations including the Nail Manufacturers Council and the Professional Beauty Association and the Personal Care Products Council. OPI, since it started in 1981, has been working very hard to provide knowledge and education to salon professionals. OPI was acquired by Coty in December of 2010.

I know that we’ve talked a lot about nail products today. So this might be a little bit of an overview, but I
wanted to make sure that everyone was on the same level. So this is just a little bit of nail product 101. Please get your books out, but you can take some notes on this in case you needed some idea on nails.

Solvent nail enamels are what you think of when you think of nail polishes. Everything that you see out there, a lot of them are solvents. They come up with four different parts, you have a solvent, a film former, the plasticizer, and the pigment. This is what you see out there the most. There's a large range of brands from large companies to small companies. And the solvents are the major component of the product and it's used to dissolve the polymers and suspend any of the added pigments until application. And those pigments are what everyone goes after so those are the colors and the effects that you are going to see on the nail.

The new product categories are the UV-cured nails. I don't know how many people have seen all the ads recently, but these are things that last longer than seven days on the nail. They don't start with a solvent, they actually start with monomers. And they use the UV or LED lamp to photo initiate the monomers, that allows them to link and it creates more solid film on your nails. And that polymer network holds the color and shimmer particles in place. It creates a very hard film on your nails and it lasts, in most
cases, up to two weeks.

The kind of the older version of these long-lasting nail products are the acrylics. They’re still out there in a professional setting, but you don’t see them as often anymore. Those are generally made up of two separate portions. There’s the liquid portion and then there’s the powder portion of the system.

In the liquid portion, a catalyst interacts with the benzoyl peroxide that you’re going to find in the powder portion to create the needed energy to create the polymers that creates the base of the nail.

And then in the powder, the polymer is usually either a poly ethyl methacrylate (or poly methyl methacrylate) or a blend of the two, along with the benzoyl peroxide to create the overall look. And then, of course, you have those pigments that we discussed earlier, the titanium dioxide, mica, and the D&C and FD&C approved pigments which we’ll get into later.

The other major category I wanted to discuss briefly are bonders and pre-primers. You’ll see these primarily also in salon nails. The bonders help bond the monomers better to the nail so that you have a longer lasting nail finish. And you also have pre-primers that help make the nail surface more alkaline before priming.

Now that we all have a general level setting of
what nail products are, I wanted to go into a deeper dive on
the chemicals in nail products. This is somewhat very
similar to Eric’s presentation earlier. As we discussed,
there’s a variety of solvents, plasticizers, film formers,
and colorants that are found in nail products. And, as
we’ll all hear, there’s additional scrutiny on some of those
products. We’re going to go into a little bit more detail
on dibutyl phthalate, toluene, formaldehyde, triphenyl
phosphate, and a variety of colorants.

The first, dibutyl phthalate, otherwise known as
DBP, was used in nail polish, top coats, and base coats. It
is a plasticizer. We’ve heard that today already. Safety
concerns, estrogenic effects when used at high dosages.
However, a study done showed that in order for the human to
get the right level for it to be toxic, we would have to
ingest five bottles of nail polish every day. So it might
be toxic at a hundred percent, we’re not using it at that
level. The EU cosmetic directive, or EU cosmetic
regulation, banned the use of the dibutyl phthalate in 2005
in nail polish use. However, quickly following the EU
Scientific Committee on Consumer Safety, or the SCCS,
published a report demonstrating the safety of the
ingredient. The ban was not overturned; however, the safety
study’s still out there. You should know that Coty
reformulated out of dibutyl phthalate in 2008, along with
most of the major nail manufacturers out there.

Toluene, another one of the toxic trio was used in nail polish, base coats, and top coats. It is a solvent. Again, at high exposure levels, it can present a cancer and a reproductive system risk. A study done by the State of California showed that that at the average toluene exposure levels, an average work technician would have only received 1/200th of the OSHA safe exposure level. So again, the risk is really not there.

Regulation against toluene, there really hasn’t ever been set regulations against toluene; however, the consumers are very vocal about what they’re looking for. Therefore, Coty voluntarily ceased the use of toluene in 2012. Again, you will not see toluene in most major nail polishes or manufacturers.

The next one, formaldehyde. Formaldehyde is used in nail hardeners, as we heard this morning. It acts as a cross linking agent that stiffens the nail, fingernail protein. It’s linked to a rare nasopharyngeal cancer when large amounts of formaldehyde gas are inhaled in industrial settings. The OSHA 8-hour workday standard for formaldehyde exposure is .75 parts per million, almost 200 times higher than the highest level in the OSHA study which is .0038 parts per million. This is why a risk is a really important aspect to the risk hazard safety assessment.
U.S. and Health Canada both allow up to 5 percent of formaldehyde in nail hardeners. And the European Commission, again the European Commission Scientific Committee for Consumer Studies, the SCCS, so they say up 2.2 percent of free formaldehyde can be used to safely strengthen nails. Coty only uses formaldehyde in nail hardeners, and it is never used in any other uses.

One of the last ones I want to discuss is triphenyl phosphate, which several people have mentioned today is a plasticizer. It has been linked in one or more studies to endocrine destruction. However, the World Health Organization has identified triphenyl phosphate as low toxicity in short-term studies. It is not mutagenic, it does not cause delayed neuropathy or neurotoxic changes. Also, triphenyl phosphate does not meet the criteria for persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substance, per the UK Environmental Agency. And OECD has identified the material as a low hazard.

Overall, there are no regulations against triphenyl phosphate in the cosmetic industry. Additionally, the U.S. FDA allows triphenyl phosphate as an indirect food additive when it comes to food.

I wanted to give everyone a little bit of background on colorants. So all colorants used in U.S.
cosmetics must be approved by the FDA. There are two
classifications of colorants. There are those that are
exempt from certification and those that require
certification by the FDA. Those exempt from certification
are the ones that you see with the names of iron oxides,
ultramarines, ferricyanide, and titanium dioxide.

So the FDA, you can go to their website, maintains
a positive list of these colorants and their permissible
uses. Some of them can only be used in the eye area, some
can only be used on nails. They’re all on the FDA website.

The second classification are the batch certified
FDA colorants. For a manufacturer of a colorant, they have
to provide a sample of the batch to the FDA who then does a
test on it to ensure purity and that heavy metals are within
the requirements. This is done on every single batch and
the manufacturer of the finished goods actually gets a copy
of the certificate and it’s contained in their records. Not
only are the FDA very specifically looking at colorants, the
actual manufacturer of the product is looking at them as
well.

For example, as we’ve mentioned, the industry is
extremely global. So not only are we selling our products
in the U.S., we’re selling them in Japan, we’re selling them
in the EU. Therefore we ensure that our products meet the
industry standards set forth by the EU Cosmetic Regulation
as well as the Japanese Administrative Health. There’s also
an additional level of this so it’s great that so many
different countries have regulations, but Coty also has
internal standards as many other cosmetic companies do. We
have very strict purity and heavy metal content that must be
followed for every single material that goes into our
product as well as the finished good.

Manufacturing and quality control is the next
section. Nail lacquer formulas as really unique. They are
not like a body lotion, they’re a little bit more difficult
to make. In most cases, you go to specialized third-party
manufacturers to create the bulk. But it’s not as if we
just go the manufacturers and say, make this formula, give
them the formula and we’re going to market it. Before
anything actually gets awarded to a third-party
manufacturer, a company is going to send them their own
quality control and make sure that a whole audit is done; so
that they’re meeting all of their requirements. We only
manufacture using manufacturers who are GMP compliant. Many
of them are also FTA OTC certified facilities and ISO
22716:2007 certified. We ensure quality from numerous
different standpoints. Not only do we ensure quality from
the actual manufacturing standpoint, when the bulk of the
finished good then comes back into the Coty facility, we do
our own set of quality controls. Through SOP following, we
ensure that the product evaluation and the quality assurance standards are met. Nothing goes on the market without all of these standards being met from both the raw materials to the finished good.

Today we’ve talked a lot about safety which is extremely important to Coty and to anyone that sells a product in the U.S. The FDA requires that you are able to substantiate the safety of your product prior to putting it on the sale, prior to putting it on the market. The EU took it one step further and requires the creation of something called the product information package or PIP, it goes through numerous different names. This was passed through the European Cosmetic Product Regulation 1223/2009 and it was -- became operational in July of 2013.

What this is, is that it’s a very thick packet of every single thing that has to do with the product. You have your quantitative formula, your qualitative formula, the manufacturer instructions, your product specifications, your bulks specifications, your actual packaging information, your SDSs, your raw materials specifications, and then a huge portion of the packet is the safety assessment. It goes through every aspect of that product and its exposure and its end use. They follow the SCC guidance document when it comes to exposure, and only people who can actually make the safety assessments are board
certified toxicologists or people who have diplomas similar to it. You have to take a course in Brussels that goes through all of us, it’s not easy course from what I’ve told. I have not taken it.

But what I can tell you is that all of this documentation has to be compiled and signed off on prior to the product even going on the market. So this is a requirement for the EU. It’s also a requirement for many other salon locations in the world including the Asian countries which is Southeast Asia.

Coty ensures that before anything goes on the market, a complete safety assessment is done. Also the PIP needs to be ready to go. Because if EU regulatory comes to us, we have less than 72 hours to provide it to them. That’s a really short amount of time to compile all of this information so we make sure that it’s already compiled prior to sale.

We talked about how you’re substantiating your safety assessments. We do internal studies and we also rely on external information. Prior to sale, every single one of our products are tested. And I believe that this is pretty similar to any other company within our industry. Some of these example typical tests are repeated result patch tests on nail enamel. We’ve had one study or at least one study that had 110 test subjects, the total of nine different
applications. In-use safety evaluations with dermatologists signing off on nail polish. There were 16 test subjects and a total of 8 applications. We’ve also done the in-use safety evaluation of the gel manicure systems with 34 subjects who participated in a six-week study. Nothing goes on the market without very strict safety review.

Finally, we also leverage independent studies from both U.S.-based companies and external. There’s the California Salon Formaldehyde-Toluene Safety Study that we rely on, the SCC opinion on the safety of the use of formaldehyde in nail hardeners, and the Cosmetic Ingredient Review Board which has reviewed a large percentage of the products that we use.

I only have five minutes left so I’m going to try to get through this. As I said in the beginning, OPI in our industry has worked very closely with the Professional Beauty Association and the Nail Manufacturers Association to communicate to salons. We heard earlier that SDSs are sometimes found for salons. I can tell you that for OPI, we have a database that if you’re a professional nail salon or if you are a distributor of our product, you log on, you can get every single SDS that you want. Many of them are translated in other languages including Vietnamese.

Additionally, on the PBA and NMC websites, there are 18 different guidance documents coauthored by OPI
employees that communicate to salon owners. This goes through ergonomic basics, cleaning, disinfecting procedures, steps to minimize inhalation and skin exposure. I know the slides are going to be posted but in the annex of this, I go through every single one of them and what their topics are. Amazingly enough, all of these are translated into Korean, Russian, Spanish and Vietnamese. We know it’s a very ethnic population who is actually doing the applications; they all need to have access to this information.

The EPA has also released a guidance document in March of 2017. Sorry, in March of 2007, protecting the health of nail salon workers. Topics include best shop practices, gloves, masks, respirators, and liquid methyl methacrylate monomer fact sheet.

Very quickly, microtrends in nail products. Consumers drive our industry, obviously, so right now the current solvent-based formula technology provides a manicure that suits the consumer needs. We have found in our studies that the alternative technologies do not meet the performance or the needs of the consumer in the solvent-based technology. Therefore, they’re not reproducible and not a good alternative on the market. An example of these are the water-based nail colors, and I believe the group from Harvard had shown that many of those who come out as saying that they’re safer or green might be providing a
misconception out there to the market.

In conclusion, the global cosmetic industry is subject to national and international rules that regulate and govern the safety and efficacy of our products. While specific requirements may vary from country to country, product safety and regulation compliance is essential. No products should be going on the market if there’s a safety concern. Many of the ingredient concerns discussed today have been proven to be false or unfounded by international bodies.

Coty, along with other multinational companies, work with industry to publish guides in a variety of languages to ensure worker safety.

Thank you.

MS. RUBIN: Thank you. At this time, we’re going to take any questions or comments that we have for Katherine. We’ll start with folks in the room and Doug had your hand up first, so we’ll start with you.

MR. SCHOON: Doug Schoon, Professional Beauty Association. Excuse me, as I cough through.

We talked in last section about IFRA. Under this science-based organization, there’s a tremendous amount of research into fragrance ingredients. And the purpose of that research is so they can make recommendations to manufacturers about the safe levels of fragrances. I know
you’re not a formulator, but can you tell us if Coty adheres to the IFRA guidelines when they decide how much fragrance to put in the products?

MS. MONTGOMERY: Yes, everything that we manufacture meets IFRA standards. You actually in most countries cannot even sell in those countries without providing an IFRA certification. We rely on the fragrance houses whose trained toxicologists only look at fragrance ingredients. And they help us determine what the best level is dependent on the IFRA standards. Every single thing that we manufacture goes by the IFRA standards.

MR. SCHOON: Thank you.

MS. RUBIN: So for folks on the phone, his question --

MS. MONTGOMERY: Sorry.

MS. RUBIN: -- was about IFRA standards. It’s okay if you want to repeat it, I don’t mind.

MS. MONTGOMERY: Okay. Sorry.

MS. RUBIN: Go ahead and repeat if you don’t mind his response.

MS. MONTGOMERY: Yeah, of course.

MS. RUBIN: Okay, great.

MS. MONTGOMERY: The question was specifically about whether or not we follow IFRA standards because IFRA does a large amount of studies on safety of fragrance
ingredients.

MS. RUBIN: Our next question will be over here.

MS. PORTER: I’m Catherine Porter with the California Healthy Nail Salon Collaborative and I have a sort of a two-part question. One is, I see the third bullet down on your conclusions, I’d be interested in seeing the studies that you’re alluding to there that prove things discussed here today are false or unfounded. Will you be posting that along with your presentation?

MS. MONTGOMERY: The question is regarding my statement that many ingredient concerns discussed today have been proven to be false, unfounded by international bodies. And to answer your first question, the presentation will be posted.

To go back, I provided the references associated with the studies that I cited when it came to ingredient safety. From a cosmetic standpoint, we always take risk into consideration when doing safety assessments. Therefore, in the formaldehyde study by the European Scientific Committee on Consumer Safety which is a publicly available study -- I’m more than happy to send it to you, if you would like -- showed through numerous different studies that formaldehyde was safe up to 2.2 percent. And it also has pointed out that formaldehyde is naturally occurring in foods and formed in mammals, including humans, and it’s not
a problem from a human safety perspective. Also, for dibutyl phthalate, again the SCC report is out there, it’s publicly available and it shows that there’s a safety of the ingredient even after the ban.

MS. RUBIN: Okay. And --

MS. PORTER: Can I just follow up?

MS. RUBIN: You have a follow up?

MS. PORTER: Maybe you can talk a little bit more about you’ve mentioned showing safety, proving safety, certifying safety. And I’m curious if that safety speaks to chronic effects such as cancer, reproductive harm, respiratory problems, asthma, neurological problems, things like that.

MS. MONTGOMERY: I’m not a toxicologist. Oh, the question is whether or not we’re looking at repeated exposure. I’ll admit that I’m not a toxicologist, I’m in regulatory. However, I do not that the SCC and other certified bodies do look at repeated exposure. I can definitely look into that and provide more information.

MS. PORTER: Well, repeated exposure with the result of being chronic illness like cancer --

MS. MONTGOMERY: Yes.

MS. PORTER: -- reproductive harm.

MS. MONTGOMERY: I under -- I do know --

MS. PORTER: Etc.
MS. MONTGOMERY: -- the SCC does look into that, but again, as not a toxicologist, I don’t feel it’s right for me to comment.

MS. RUBIN: We had another question up front and then we’re going to go this side and then back over to Angie.

MS. ALCANTAR: This is Kathryn Alcantar, with the Center for Environmental Health and the CHANGE Coalition. I have a question similar but maybe slightly different to Catherine’s which is for the safety studies that you referred to that have been done, are those just for consumers of the product or are they also for workers?

And then, does it also include, as seeing now more children using nail products in particular, have those studies also been considered, exposure to children and their unique vulnerabilities?

And then finally, have those studies also included aspects of multiple, you mentioned repeated exposure, but as was shared earlier, it’s also from multiple contaminants, right? Multiple chemicals. I’m wondering if your health and safety studies that have been done prior to going to market also look at mixtures, if you will, of various products being used in the workplace and on consumers.

MS. MONTGOMERY: One of the first questions was whether or not we test our products and investigate the
safety on children. None of the Coty products from our entire category are to be sold to children. It is part of what we do; so, we’ve not looked at the safety of children. It’s actually not ethically sound to test on children as within our testing methods.

Another one of the questions was whether or not we investigate the safety from a safety worker perspective. During application and also during the creation of the instructions, the safety of the workers are considered and that’s why safety guidance documents and the safety instructions are written to that prospective. We have sales associates who go out to the salons and demonstrate how the how the products should be applied safely.

In terms of repeated exposure, again, that’s a great question and something I’m going to have to look back at.

MS. PORTER: Can I just ask a follow-up question which is, is there a way to ensure that children aren’t using the products that you create that aren’t supposed to be sold to them? Are there manufacturers looking into that?

MS. MONTGOMERY: From my perspective, they’re not looking into that. But, to be honest, there’s really no way to control anyone from using a product; so, that’s part of a double-edged sword. You could ask if anything could be used by a child. I don’t think that’s necessarily a fair
question.

MS. RUBIN: We’re going to go to this side first and we’ll try to get around to all of your questions, but we only have five minutes left so let’s all try to be as concise as we can. Thank you.

MS. LITTLE: Just to reiterate concern about making sure if the studies were pertaining specifically to the worker population, but you said that as manufacturers, you do give guidance as to how the workers are supposed to be using the products.

MS. MONTGOMERY: Uh-huh.

MS. LITTLE: Do you have any follow-up data as to whether or not they actually use the product that way? And if they don’t, then what are they exposures? What are they exposed --

MS. MONTGOMERY: The question is whether or not we have follow-up data to show whether or not the salons are using the products correctly. I don’t have that in front of me right now. I can tell you that we do have a consumer affairs hotline where we do get questions from consumers, we provide additional guidance. Also OPI and Coty don’t own the salons. We can provide guidance, but we can’t necessarily dictate exactly how they operate.

MS. LITTLE: And then, do you have follow-up data if those guidelines aren’t being complied with? What are
the effects? What is the potential risk to the workers
without the complying to guidelines, from just the regular
exposure?

MS. MONTGOMERY: I don’t have that information.

MS. RUBIN: We’re going to take a question from
this gentleman, then we’re going to go back over here and
try to get you in as well.

MR. KING: Andrew King with DTSC.

I have a two-part question. The first is you
mentioned reformulation. I’m just curious, in the industry,
how frequently it happens, where with a typical product, how
frequently is reformulation of the ingredients for the same
product? That’s the first question.

And the second is, with your third-party
manufacturers, if you can you tell us a little more about
the quality control. Are you literally testing to make sure
the ingredients they said they’re putting in it is going in
there? Is that part of the testing?

MS. MONTGOMERY: The first question is regarding
reformulation, how often it occurs. Reformulation occurs
for a variety of reasons. Very rarely is it a safety
reason. It wouldn’t be on there. A lot of the time it’s
change in regulations, it’s for a cost savings, it’s the
fact that a raw material supplier has stopped actually
selling the raw material. I would like to say that it
doesn’t happen that often, because it’s a huge undertaking. It’s usually not only changing the product, you have to make sure that it’s performing as well as your previous product so that you’re not losing consumers. And, also, you’re changing all of your labeling which is not an easy feat to do when you have such a large product line.

Reformulations are very driven by numerous different functions. Again, very rarely is it a safety concern. When it comes to the quality controls, what I can tell you is I know it’s not publicly available information but we did have one of our third-party manufacturers, on our behalf, submit confidential information on their quality and manufacturing processes to DTSC. I don’t remember who that went to. I think it might have been you.

MS. PAPAGNI: Right. We haven’t received it yet.

MS. MONTGOMERY: I can follow up with them as well if it’s still not there. But we do test to ensure the ingredients that are supposed to be there are there. And also that’s part of the GMP certification. If you’re stating that you are GMP compliant, you should be following your own rules at the same time.

MS. RUBIN: We’re going to have to stop there.

Thank you so much.

MS. MONTGOMERY: You’re welcome.

MS. RUBIN: We’re going to take a break for lunch.
and we’re going to come back at 1 o’clock. We’re going to start at 1 o’clock, so if you could come back a few minutes before, get settled in, we have some more great speakers lined up for you today.

Thank you for your participation, thank you to our presenters. And we’ll see you back here at 1.

(Off the record 11:50 a.m.)

(On the record 1:00 p.m.)

MS. RUBIN: We're going to dive back in and I'm going to start cuing up our next presentation. I want to introduce now Catherine Porter, the Policy Director of the California Healthy Nail Salon Collaborative. Her presentation is titled, The Chemical World of Nail Salon Work, Practice, Processes and Toxic Products.

We're just going to take a couple minutes. A lot of people are filing back into the room. For those of you online, Catherine will be giving her presentation shortly.

(Pause)

MS. RUBIN: If we could have everybody settled and give our full attention to Catherine, we're going to start now. Thanks very much.

MS. PORTER: Good afternoon, everyone. Hope everyone had a good lunch and is not too relaxed, so that we can all pay attention during the second half. I'm Catherine Porter. I'm the Policy Director for the California Healthy
Nail Salon Collaborative, and today I'm talking about The Chemical World of Nail Salon Work, Practices, Processes and Toxic Products.

At some point I'm going to give you a really bird's eye view of what a process in a nail salon looks like. The California Healthy Nail Salon Collaborative was formed in 2005, composed of public health and environmental advocates, nail salon workers and owners, community-based groups and allies in government agencies.

Our mission is to protect and improve the health and safety and rights of the nail salon community. We do our work to benefit working women like the one whose quote we see here. The woman whose quote we see here started out as a nail salon worker for a few years, and then has been owning her own nail salon for several, and she is a Vietnamese immigrant.

Most nail salon workers and owners, at least in California, are Vietnamese immigrants. Most are women. Many are of reproductive age, and language can be a barrier to accessing information about state and federal labor and occupational health laws and regulations designed to protect their rights and safety.

Nail salon workers may work as many as six days a week, eight or 10 hours a day. While many of the acute symptoms, such as headaches, dizziness, rashes, respiratory
problems, watery eyes and watery nose experienced by nail salon workers is well-documented, nail salon professionals are concerned are potential chronic harms, including those related to the reproductive system.

Nail salon workers are calling California Occupational Health Hazard hotlines in significant numbers to make pregnancy-related inquiries. Some technicians say they plan to quit their jobs when pregnant to avoid toxic exposures. And there is reason for concern.

Although there is not a tremendous amount of research on the issues, we do know that chemicals are getting into nail salon workers' bodies and that many of those chemicals can be harmful. As an example, phthalate levels in the body have been found to be higher in nail salon workers relative to the general population.

And as far as harm, studies have shown a positive association between phthalate exposure levels and adverse reproductive outcomes such as pre-term birth. And just recently, I believe last week, the EU decided to recognize dibutyl phthalate and three other phthalates as endocrine-disrupting chemicals for humans under the EU's REACH regulation.

A 2014 study found that manicurists in California are at greater risk of pregnancy complications such as placenta previa, as well as diabetes, gestational diabetes,
premature rupture of the membranes, low birth weight and small for gestational age, compared with the general population for all races combined.

And while studies that quantified toxic exposure in nail salons are wanting, chemicals of concern have been detected by air monitoring in salons. Every day nail salon workers and owners are served up toxic cocktails of potentially harmful ingredients.

Here, for example, are the various products used in a pedicure with traditional polish, and this is an example of a pedicure I personally just went through. The technician was a woman of Vietnamese descent. She spoke a little English and we were able to have a conversation.

She came to the United States as a refugee from Vietnam, stopping on the way in the Philippines in a refugee camp before she came to the United States. She got into the nail salon work because she could be trained for it. English language wasn't essential. For many women in the Vietnamese community nail salon work is their route to some sort of economic security.

First, there's polish thinner, which may be used if a polish is too thick to spread. And thinners often have toluene or methyl ethyl ketone, both of which are neuro and developmental toxicants among other health concerns, and both are on the DTSC Candidate Chemical list.
And I'm going to be mentioning that list quite a few times, and so to avoid tongue-tying myself with Candidate Chemical list, I'm just going to say CC list. So everyone knows now what I'm going to be talking about. Then after the polish is thinned, polish remover may have to be applied if there's nail polish already on the toes.

And polish remover often contains significant amounts of acetone. Although an alternative may be with ethyl or butyl acetate may be better as far as human health impacts, both are prohibited from polish by the Air Resources Board's Consumer Product VOC limit. Acetone, on the other hand, is an exception to that regulation.

Then after the nail polish is removed, cuticle remover or softener is applied to work on the cuticles. A 2012 safety data sheet for cuticle remover listed, among other chemicals, methyl ethyl butyl propyl parabens, which may be reproductive toxicants and endocrine disrupters, they're also on the DTSC CC list and are priority chemicals for California Biomonitoring Program.

And this product also contained fragrance, and we heard a presentation about potential impacts of fragrance earlier, and we also heard that they are not required to be disclosed. The product just contained the general listing of fragrance, and who knows how many components and how dangerous those components are.
Then after the cuticle remover or softener, cuticle oil or a scrub product is often used, and they often contain fragrance, and quite a strong fragrance, I might add. And then comes sort of the main event, which is the base coat, the color coat and the top coat.

And the ingredients for those products are pretty similar, if not identical. In fact, I believe Creative Nail Design makes a safety data sheet that is supposed to reflect ingredients in base coats, top coats, and nail lacquer.

Some of the ingredients in base coat, top coat, and nail lacquer include solvents, and that makes the polish spreadable. And examples of solvents in nail salon products are toluene, which is a reproductive toxicant, and isopropyl alcohol.

Resins have the function of reducing brittleness and improving adhesion and create a more durable polish. An example of a resin is tosylamide formaldehyde resin. That may be a skin allergen for some, and one study showed that the higher the tosylamide formaldehyde resin levels in polish, the higher the formaldehyde level in that polish also.

Plasticizers are added for flexibility and reduce brittleness. Examples of plasticizers, which you've heard of today, are dibutyl phthalate, which is a reproductive and development toxicant; we've also heard about triphenyl
phosphate, which is a suspected endocrine disrupter, and a recent Duke University study showed that TPP can be absorbed through the nail or skin of customers.

And rounding off the content of polishes, there are pigments which can contain harmful metals. And then after the coat is applied to speed up the drying process a nail dry aerosol is often applied which contains t-butyl alcohol and butane, both of which are DTSC Candidate Chemicals.

Then after the customer steps away from the pedicure booth, the nail salon worker or owner has to scrub the tub, and they have to use a hospital grade disinfectant. They have to do that after each client and they have to do that at the end of the day, according to state agency rules.

And then they have to do it once a week. They have to fill the tub with this hospital grade disinfectant and leave the disinfectant in the tub for six hours in order to comply with Board of Barbering and Cosmetology Rules. All during that time there are exposures to not only the nail salon worker, but any customer that's in a salon.

That's just a pedicure service using traditional polishes. There are also artificial or acrylic nail services, which for many nail salons are really the bread and butter of their businesses. Artificial nail systems grew out of dental technology used for bridges and crowns.
Many major nail product companies started in dental products before branching out to cosmetics. OPI, for instance, originally stood for Odontorium Products, Inc. There are basically two types of artificial nail services. The term "acrylic" usually refers to liquid and powder mixes, which are combined by the nail technician into a dough and shaped onto the nail with a brush and then air dried.

Gel nails, the newest product, are painted on from a container of already mixed dough. Now, gel nail services avoid the nail technicians having to mix the powder and the liquid monomer and the consequential exposure. However, gel nails require multiple rounds of exposure to UV or LED light, and LED light also contains UV light, to cure or dry the artificial nail covering.

And this is especially concerning as UV rays are carcinogenic. Plus, we have no idea what synergistic effect there may be when UV light and these chemicals come together. Sometimes, the gel products are touted as a safer alternative to acrylic nails, but we have concerns about both, since both gel and acrylic nails contain methacrylates.

Methyl methacrylate or MMA, is irritating to the skin, eyes and mucous membranes in humans, an allergic response to dermal exposure may develop and there are
respiratory effects, such as occupational asthma. Respiratory symptoms observed following acute exposures include chest tightness, coughing, wheezing and reduced peak flow.

Neurological symptoms such as headache, lethargy and lightheadedness have also been reported in humans following acute exposure to MMA. And MMA monomer is prohibited from use in California nail salons by the State Licensing Agency, but it's prohibited due to the harm that resulted several years ago to the nail beds of customers, not because of any potential harm to the nail salon workers.

EMA, or ethyl methacrylate, is often used as a substitute, but EMA raises similar concerns as far as allergic contact dermatitis and occupational asthma, but to date there is little, if any, study as far as we know regarding the relative safety of MMA versus EMA, or the many other methacrylates, and as time goes on one is being replaced or substituted out for another.

And another problematic chemical in artificial nail products is the carcinogen N, N-Dimethyl-p-toluidine, which is also on the DTSC Candidate Chemical list. It's used as an accelerator in the curing of methyl methacrylate monomers and is a substance of concern for workers and consumers, as exposure routes include not only inhalation, but also possibly through skin absorption.
The backdrop to this not so jolly chemical cocktail party at nail salons is that industrial chemicals in cosmetic products are largely un- or under-regulated in the U.S. Of the 10,000 chemicals used in personal care products, including nail care products, only 10 percent have been assessed for safety.

When it comes to cosmetic products the federal FDA law prohibits the marketing of adulterated and mis-branded cosmetics in interstate commerce. Adulterated signifies whether it contains a poisonous or a deleterious substance, and it's usually connected with more acute reactions.

Currently, there's no requirement that the FDA assess the safety of cosmetics products before they go on the market. There's no mandatory recall authority for the FDA if a product is unsafe, and fragrance components do not have to be disclosed, as you heard earlier.

And due to a large loophole in the labeling laws, manufacturers of professionally used cosmetics do not have to list the ingredients on the labels. And on the state level there's the Sherman Food Drug and Cosmetic Law that pretty much tracks the federal law, the Safe Cosmetics Act and Program -- someone will be talking about that program later today -- and then Cal OSHA law, which sets exposure limits for many chemicals.

And it was referred to today as sort of a
touchstone to show that a chemical is safe if it's below Cal
OSHA limits. However, Cal OSHA limits and OSHA limits are
woefully out of date. In fact, if you go to the OSHA
website you'll see that the agency itself says that these
exposure limits are out of date.

And many of the exposure limits with OSHA or with
Cal OSHA are not based on chronic harm. They're based on
acute harm. So you've heard something about healthy nail
salon recognition programs. The Collaborative started
advocating for those about five, six years ago.

Now, there are five cities and counties in
California and about 130, 140 nail salons total that are
trying to use less toxic products, and this dovetails very
nicely with AB 2125, where DTSC is going to be involved in
this effort, and then this program with DTSC to try to find
safer alternatives.

And we know that nail salon workers and owners
want safer products. We've done surveys of consumers and of
healthy nail salons. They say they're willing to pay more
for healthier products. Nail salon owners say their
business goes up. So safer products, as hopefully this
process will result in, is a win/win for everyone.

To close, the Collaborative and our Research
Advisory Committee and our various scientific and policy
partners really believe that ultimately, DTSC, assuming it
does pursue nail products, look at chemicals as a group, as
groups of chemicals and not as individual chemicals.

Some of the groups that DTSC might target would
include plasticizers, methyl methacrylates, resins,
solvents, phthalates, and fragrances. The Collaborative
believes it's better to be safe than sorry when it comes to
health of women workers, especially the most vulnerable,
like nail and other salon working professionals. And we're
hoping that you all here today and DTSC agree with us on
that. Thank you.

MS. RUBIN: Thank you, Catherine. At this time
we're going to take questions and comments to Catherine's
presentation. If you'd like, I can repeat the question or -
-
MS. PORTER: Sure.

MS. RUBIN: Okay. So I'll repeat the question
asked or comment for those on the line, and we will have 10
minutes now. So does anyone have any comments or questions
in the room? Yes.

DR. SINGLA: Thank you for the presentation. You
mentioned a --

MS. RUBIN: Could you -- oh, sorry. Can you
identify yourself and your affiliation?

DR. SINGLA: Veena Singla, with the Natural
Resources Defense Council. Thank you for the presentation.
You mentioned a number of different chemicals of concern in these salon products. Could you speak a little bit about -- what do you know about the placental health effects of exposure to these many different chemicals at once, and what are some of those concerns?

MS. RUBIN: Her question was about the health effects to potential exposure or to exposure --

DR. SINGLA: Of many different chemicals.

MS. RUBIN: -- to exposure of a combination of all these different chemicals.

MS. PORTER: We don't know much, if anything. That's a great issue and it's an issue I think that's come up here today. These chemicals generally are looked at as individual chemicals and not as chemicals that may be interacting with other chemicals.

I mentioned the issue of UV light interacting with chemicals on nails. That's an issue that has not been looked at. And then, of course, just your hodge-podge, your cocktail of chemicals and how they interact or react with others has not been looked at, as far as we know, although there was much reference to studies or certifications that show safety of products.

Again, we'd love to see those studies and we'd love to see if any of those studies look at chemicals in conjunction with other chemical exposures.
MS. RUBIN: Okay. On this side.

MS. POWDER: Jill Powder, Environmental Health Decisions. This is more of a comment than a question. I would imagine the only way to address that question would be through some kind of epidemiological study where they're actually looking at, here's the concentrations of chemicals x, y, z, a, b, c, d in the air at the nail salon, and here are the potential health effects of the workers there that are exposed eight hours a day, five days a week.

I mean, short of that, I can't think of any other way to find an answer to that question.

MS. RUBIN: Her comment was a response to the first question asked, and it was a recommendation for an epidemiological study based on nail salon workers and the chemicals they interact with.

MS. POWDER: And actual air concentrations.

MS. RUBIN: And actual air -- and indoor air, sampling.

MS. POWDER: And exposure scenarios.

MS. RUBIN: And exposure scenarios.

DR. SINGLA: And could I just add one more comment to that?

MS. RUBIN: Yeah.

DR. SINGLA: This is Veena Singla again, with the NRDC. Thank you for the comment. I agree that this is
certainly an area for more research, but I think the studies that we do have on a number of these chemicals together do indicate cause for concern.

For example, let me think about VOCs and total VOC content. There is definitely evidence that total VOC exposure can be attributed to respiratory irritation. With the phthalates, as well, there's definitely concern for a cumulative exposure to multiple phthalates that act together to impact the same health end point.

MS. RUBIN: Her comment was on exposure to multiple chemicals and the knowledge that we do have. There are studies that show exposure to multiple chemicals, like different types of phthalates and VOCs, can in fact help. Is that accurate?

DR. SINGLA: Yes.

MS. RUBIN: Okay. Good. Just making sure. I believe you were next.

MS. LITTLE: Yeah. Catherine, at the beginning of your presentation, you talked about some studies that had been done with regard to the effects or the health concerns among nail workers. How close did those studies match something that she's talking about?

MS. RUBIN: Okay.

MS. LITTLE: I guess my question is, can you talk more about the studies that you all have done with regard to
the nail salon population in terms of the overall health
effects, as we would assume they would all be exposed to
this cocktail of chemicals.

MS. RUBIN: So again, that's Susan Little.

MS. LITTLE: Susan Little, with the Environmental
Working Group.

MS. RUBIN: Okay. And your question was?

MS. LITTLE: Was to explain more about those
studies that she brought up in the beginning, and how they
illustrated the effects of the chemicals that the salon
workers were exposed to.

MS. RUBIN: She's looking for a more in-depth
explanation of the studies referenced earlier in your
presentation on how the chemicals affected --

MS. LITTLE: Affected salon --

MS. RUBIN: -- the workers.

MS. LITTLE: Yeah.

MS. PORTER: I believe it was the study that
looked at the large world of cosmetologists and nail salon
technicians licensed through the BBC throughout California.
It wasn't individual nail salons looking at individual air
levels at individual nail salons.

It was just a study that looked at whether
reproductive concerns are prevalent in the nail salon and
cosmetology world, and how prevalent are they compared to
the general population. And it determined that there are several types of negative reproductive outcomes that are more prevalent among nail salon workers.

And in fact, specifically among Vietnamese nail salon workers there was information. I believe that was small for gestational age, was something that was unique, even to Vietnamese nail salon workers.

MS. RUBIN: Okay. Angie.

MS. PEREZ: This is Angie Perez, Cardio ChemRisk. I have a couple questions. The first is: are you exploring any sources of funding for biomonitoring through this program?

MS. RUBIN: Her question for Catherine was, are you exploring any sources of funding for biomonitoring for this program?

MS. PEREZ: It just seems like such a perfect setup for it.

MS. PORTER: Well, this program, meaning the Healthy Nail Salon Program?

MS. PEREZ: Um-hum.

MS. PORTER: We are not. There have been biomonitoring studies, though, that did show high levels of various chemicals. It's not as if that hasn't been done. Our organization is a small nonprofit and we depend on foundation funding.
And so I'm sure if there were any manufacturers that would be willing to donate some money for us or for the state to do a biomonitoring study that would be great. There is a biomonitoring program in California. So I'm sure that program could also use some funding, also.

MS. RUBIN: And did you have a follow-up question to that or was that --

MS. PEREZ: I do, but it was unclear.


MS. GRESS: Ky Gress, from Safer Consumer Products. I have a question. Would it be feasible for your organization to collaborate with a college of public health to do large-scale surveys in nail salons through California to try to get some of this epidemiological data, fill in the gaps? Would it even be feasible for your organization to collaborate on that level?

MS. RUBIN: So the question was about collaboration with colleges or other organizations to --

MS. GRESS: Collect data.

MS. RUBIN: Collect data.

MS. GRESS: Go into those salons.

MS. RUBIN: And --

MS. GRESS: Collect health, potential health effect data.

MS. RUBIN: And organize a biomonitoring --
MS. GRESS: No, not biomonitoring.

MS. RUBIN: Oh, it's not -- epidemiological.

MS. GRESS: Just literally surveying potential --

MS. RUBIN: Okay. So a literal survey by colleges or other organizations of --

MS. GRESS: I'm just -- no. Really. It just seems like it would -- might be a fit, your organization, your staff, a college of public health and your organizational and staff going into the salons, facilitating the gathering of survey data to help fill in some of these gaps.

MS. PORTER: Right. I can answer that. I think I mentioned we've done one set of informal surveys or what I characterize as informal, with our Healthy Nail Salon Program, nail salons, and elicited and received some information through that.

The nail salon community, like many small worker communities or immigrant communities, have their sets of unique characters that make the process of surveying different and more time-intensive and requiring more in relationship-building and outreach with our bilingual staff than, say, if a community was all English-speaking, U.S. born.

I'm sure if an agency or a foundation was interested in providing us money and providing us more staff
to be able to do that sort of bilingual, cultural, sensitive outreach on a large scale, maybe in conjunction with DTSC and its AB 2125 Program, I'm sure we wouldn't turn away from that. But that's a significant amount of resources that we would require to participate in that.

MS. RUBIN: We've got time for one more, and okay, Angie. All right.

MS. PEREZ: I just had one follow-up question about one of the endpoints that you mentioned, placenta previa. Whereas, you mentioned that that was a potential adverse health outcome as a result of exposure, do you know if that study controlled for genetic or population-based risk factors? Because it's my understanding that Asian women generally have higher rates of placenta previa than their white counterparts.

MS. PORTER: I --

MS. GRESS: So -- we got to repeat the question.

MS. RUBIN: Sorry. We're going to repeat it.

MS. PORTER: Oh, I can repeat the question.

MS. RUBIN: Okay.

MS. PORTER: The question was about asking for a few more details about the study that looked at the nail salon community, nail salon technicians and their higher levels of negative reproductive outcomes, including placenta previa, and specifically, placenta previa.
I don't remember offhand. I actually have a copy of the study with me. I'd be glad to -- I'm not sure I'd be glad to give it to you, just because I like to hold onto my hard copies of things.

MS. PEREZ: You can just tell me --

MS. PORTER: But if I got your email I'd be glad to send you that study and you could take a closer look at it, yeah.

MS. PEREZ: Okay.

MS. RUBIN: Okay. So thank you very much. Thank you, Catherine.

MS. PORTER: Thank you.

MS. RUBIN: We're going to move on to our next presentation. Our next presenter is Tom Myers, EVP-Legal and General Counsel for the Personal Care Products Council. His presentation is about The Safety Behind Ingredients in Nail Products.

MR. MYERS: Good afternoon, everyone. Thank you for being here. Thank you to DTSC for inviting me to do this, Christine, too, although probably reluctantly agreeing to let me up here. I think that it's really important and very helpful to have these conversations and these types of workshops where we kind of come together and talk about these things.

Especially because of the diversity of opinion in
the room, there is certainly a tendency for people to hear from an industry representative or an NGO and to not listen to what the other person is saying. So I really do try to listen to all the different presentations, and I hope you do the same, as well, so that we can facilitate good conversations going forward.

My name is Tom Myers. I'm with the Personal Care Products Council. I'm their general counsel. We are a national trade association for the cosmetics industry. We've been around since -- a long time -- since the 19th century, and we have had a multiple number of name changes over the years.

For the last 10 years we've been known as the Personal Care Products Council. We have about 600 member companies. A majority of them are manufacturers, cosmetics finished-food manufacturers, although we do also have suppliers, as well. We have a number, like many trades associations, for those of you who -- well, most of you are probably familiar with them, but they have a variety of different departments.

Science is probably our largest one, Legal and Regulatory Government Affairs, etc. And we try to get out there and be the voice of the cosmetics industry.

A couple of things I want to talk about today and that is the following. The first is the myth that cosmetics are
not regulated. Cosmetics are not pre-approved, which may be
why this narrative seems to continue and to be, and is kind
of accepted, widely accepted narrative in the public, but
that's absolutely not true.

They are regulated. They're regulated different
than, say, a drug, also regulated by the FDA, which of
course does have pre-approval. Cosmetics do not, but that
does not mean that they are not regulated. So if you take
away anything today, hopefully, that's it.

These are the three pillars that I want to talk
about, and when I said that they were reluctant to let me up
here, it wasn't because I'm a lawyer or this is an open mic
or the fact that I'm not a scientist. It's really because I
wasn't sure, since I wasn't talking specifically to some of
the questions that were going to be presented in this
background document. I said I really want to provide some
more context, and maybe some additional points of reference
that people can refer to when they're seeking information on
some of this stuff. And so that's why they said, okay,

fine, you can come up and speak.

Let me talk first, a little bit about the
government. I'll only do a little bit about that, since we
have heard from the last speaker on that and some other
folks. I also want to talk about some third-party
assessments that are done, and then some of the things that
the industry is doing beyond what you heard today from the
representative Coty, who got up here and talked about what
the industry does and how they test for safety before
anything goes to market, what are some of the other things
that are out there that we can also look at.

Briefly, what does the law say? You heard a
little bit about this. The cosmetics products and their
ingredients have to be safe. Before they get out there you
have to be able to substantiate their safety. It's like a
post-surveillance system.

Why is that different? Why are they regulated
different than drugs? Well, FDA has come out and said,
"you're the safest product category that we regulate. We
basically have bigger fish to fry and so we don't worry as
much about cosmetics."

So they have a post-surveillance, post-marketing
effort in place, which is how they regulate things.
Companies, of course, are legally responsible for their
products. You heard a little bit about the Food, Drug and
Cosmetics Act.

What it says is that it can't be adulterated. It
can't be misbranded. I also want to mention briefly, it's
not on the slide, but the Fair Packaging and Labeling Act,
that's one of the laws that's out there that says that you
can use the word "fragrance," for example.
And I will say, I heard the discussion earlier about the fragrance issue, and in a quick plug for IFRA, another trade association out there, I think that they really struggled with how to reconcile the right to know for consumers with their trade secret information.

You have intellectual property law and this right to know kind of bumping up against each other; so, they're trying to find this balance. And so they released a palette; here's the stuff that's in it. They don't give the concentrations.

And I heard the comment that it's not trade secret. It's not like the formula to Coke. Well, it is like the formula to Coke. It is very important to these fragrance houses. That is, the value is in the fact that it is secret.

Fifty years of intellectual property law supports that. I think they have struggled with the issue. They're certainly aware of it and they have tried to find a way to address that. I just wanted to put that out there as well.

Last slide on the government's authority, but this is with FDA. What can they do? They do all kinds of inspections, they issue warning letters, voluntary recalls. Voluntary recalls are, in effect, mandatory recalls for the industry.

If the FDA is going to say, we want you to recall
something, they're not going to say no. They're going to do it. They're going to get out there and do it. I will also say there is federal legislation that has been trying to get passed to modernize the Food, Drug and Cosmetic Acts, specifically with regard to cosmetics.

Senator Feinstein, in fact, Feinstein-Collins Bill, which has been around. They've been doing this for seven or eight years now, trying to get something together and the industry has been there saying, we support mandatory reporting. We support mandatory recalls; we support all this kind of stuff.

There are a lot of things that, while it's voluntary now, the industry is behind having mandatory, as well, GMPs, etc. Other things, they can have restraining orders, they can seize products, criminal prosecution, if there's criminal negligence or intentional acts.

Imports, also, I think the most common reason that things get stopped at the border coming in from other countries is usually because they're making a drug claim on a cosmetic, that's a no-no, or it has an unapproved color additive.

You've heard again today from a couple of folks that color additives are pre-approved. You can look them up in the CFR, Title 21 of the CFR. They list them all out there. Those have to be pre-approved, and then, of course,
the drug claims are things where if you're saying something
like, my cosmetic will cure cellulite or something, or
mitigate wrinkles, you can't say that.

You can say it will reduce the appearance of
wrinkles or something along those lines, a more cosmetic-
type claims. There are lot of issues with regard to making
drug claims on cosmetics. That's another reason that
they're stopped, not because they're not safe necessarily.

The Adverse Event Reporting, this has been in the
news a lot lately. CFSAN, the Adverse Event Reporting
System, CFSAN, is the Center for Food Safety and Applied
Nutrition under which the Office of Cosmetics and Colors
falls at FDA.

CFSAN's the umbrella and cosmetics and colors
reports up to it. They have an Adverse Event Reporting
System. That information it has to do with foods, dietary
supplements, cosmetics. You can go and now it's all
publicly available, publicly searchable, and you can look
for instances where there have been complaints about certain
products, etc., etc.

It comes from consumers, healthcare professionals,
industry representatives. Anybody else that wants to file a
complaint can do so. A couple of quick stats. Looking back
at the last 13 years there have been 4,300 unique reports on
cosmetics, which results in about 340 reports a year.
That includes 1,200 reports on one single product where there was a very well publicized incident regarding a shampoo. About 70 percent of these are non-serious, like a rash or an allergic reaction of some type. I found this stat, which I liked, was 122 billion units of cosmetics were sold in 2010, which equates to 0.004 reports per million units out there.

And then if you compare that to the same thing on drugs in 2014, for example, 823,813 adverse event reports; 340 reports versus 800,000something, quite a difference. You can see why FDA has said it's such a safe category.

And the take away of that is that adverse events with personal care products are actually extremely rare. I get that the Adverse Event Reporting System, it is not perfect. It needs to be addressed and updated, and again, they're attempting to do that in the federal legislation, but it's a useful barometer for these kind of things, so.

And the bottom line, of course, is that our present practices that we're doing, both inside industry and outside, are proven to work. Okay. So third-party confirmation. I don't know. Maybe everyone knows. Maybe this is just a refresher. But the Cosmetics Ingredient Review is a third-party group that is out there that looks at all the cosmetics ingredients or has been looking at cosmetics ingredients and publishing safety data or safety
This group, Cosmetics Ingredient Review, and their website is not up there. So it's a secret. No. It's actually, I don't know why it's not there. I must have forgotten it; cir-safety.org is the website. So how did it get started?

Well, industry back in the early '70s decided that they needed some type of mechanism in place, went to the FDA and said, hey, we really think this is a great idea. We think you should assess the safety of all the cosmetics and they said, we have neither the time, the inclination nor the resources to do that, you go do it, which they turned around and did.

In 1976 industry funded the CIR. They did it with the support of FDA and the Consumer Federation of America. They tried to make it as completely independent as possible, knowing that it would be knocked as some industry hack organization, right?

Again, talking about the narratives that are out there; yes, it is industry-funded, but it is truly set up as independently as possible. All of the meetings are open. All of the reports are public and published.

There is notice and comment. Anybody can comment. Anybody can submit comments on this. This is the expert panel that actually does it: Wilma Bergfeld, who is the
Chair of the CIR, from the Cleveland Clinic, there are dermatologists, toxicologists, pathologists, and chemists. You can see all the different academic institutions from which they come, not from industries. And, then, the non-voting liaison. They represent the consumers, which is Rachel Weintraub, Linda Katz. Dr. Katz is the director of the Office of Cosmetics and Colors at FDA, and Dr. Beth Jonas, representing industries. You have those kind of three legs.

They don't get to vote, but they're at every meeting and they can represent and talk and do some things like that. So how does it work? Well, they set the priorities. They go through a process of setting priorities, which chemicals they're going to look at.

Frequency of use tends to be the surrogate for exposure. They also see if there's -- sometimes you'll see a lot of news reports or things -- red flags that pop up and they say, okay, there may be a specific concern. They take that into consideration when they're looking at these and setting priorities.

Then they go out and they canvass all the scientific literature that they can find, both published and unpublished. People can submit unpublished data, as well. Then they solicit comments. They do their findings, et cetera, et cetera. It's this whole -- as I said, it's this
very inclusive process, very open process.

And then they have a public discussion and of course make a decision, and then all of the results get published. They're not only available on the CIR website, but they -- all the final reports at least get published in the International Journal of Toxicology. So they can all be found there, as well.

Right now they've looked at about 4,800 cosmetics ingredients and each one of those ingredients, as it says up there, there can be hundreds of studies for each ingredient. If you have data that you want them to consider when they are setting their priorities, when they are looking at these chemicals, I strongly encourage you to participate and be part of this.

That's the whole point of it, is to take in as much information as possible when they're coming to their conclusions. And their conclusions are usually one of four. It's safe. It's unsafe for using cosmetics. It's safe with certain qualifications to it or there's insufficient data to come to a decision. So those are the four kinds of things that they can conclude.

Okay. Moving onto another one, INCI. I suspect many people probably know that. If you're here and you know cosmetics, you know what INCI is: the International Nomenclature of Cosmetics Ingredients; too much of a
mouthful, so it's shortened to INCI.

There is a committee that it's -- looks at -- you can make applications. You can apply for this whole naming process for an ingredient. And the reason that they have this up there is so that they have uniform, systematic names, not just in the United States on labels and for labeling purposes, but internationally, as well.

It is recognized around the world, INCI names are used on labels and in regulations. It's actually referenced. We have a dictionary. It says up there, the International Cosmetics Ingredient Dictionary and Handbook. That dictionary is published and has been every year for decades now, and it's pretty voluminous.

And it is like a Merriam Webster's on steroids. It's enormous. It's got a lot of information, as you'll see in a moment, and a useful resource, and it is. So, what is it? It's a technical compendium. It's got a lot of different information.

It's not just the genus and species and all that kind of information about the naming convention, but it goes through what the uses are, who participates in this INCI Committee. It's different trade associations, international groups, all looking to come together and it's completely science-based.

And the purpose, of course, is to have a single
reference for the name of that cosmetics and it's very
important to be talking about -- to make sure everybody's
using the same language when you're talking about something,
right.

And I was trying to think of a good example of
that on the way over today, and here's what I came up with.
I was on a family vacation in Florida and we were driving
the car and we were going through this town. My wife says,
oh, we're in Kissimmee, Florida. I said, no, it's
Kissimmee, Florida. And she said, no, it's Kissimmee,
Florida, and I said, no, it's Kissimmee, Florida.

And so we're kind of going back and forth. Then,
the kids in the back seat start getting into it. No. No.
It's Kissamay [sic], and I'm like, oh, God. This is going
on and on. I said, all right, I've had it. So I pull off
the road and I pull into this parking lot and I said, I'm
going to settle this once and for all.

And I went inside to the first establishment I
could find and I walked up to this poor young lady and I
said, can you please tell me very slowly, very succinctly,
where am I? And she looks at me and she goes, Burger King.

(Laughter)

MR. MYERS: And I said, okay. Words are
important; words are important. It's important that you're
talking about the same thing, right? So what is INCI not?
It is not an endorsement of an ingredient's safety. That is not what it's there for.

As I said, it's strictly a naming convention. It is not a pre-approved list of ingredients for any country. It's always the responsibility of the finished goods manufacturer to substantiate safety and to comply with the regulations.

These are the key takeaways for the INCI. It is a uniform ingredient labeling and the names promote a common understanding of cosmetic composition. The last point there is important, as well, consumer health benefit so that you can recognize ingredients.

For example, if you're over in Europe or something you can look at the same -- if you know you're allergic to a particular ingredient, you can find it, you know, et cetera, et cetera. It's useful. It's useful for that purpose, as well, literally a health benefit.

And then the final source that might be of use to folks, in addition to the CIR and the SCCS -- I didn't mention that. I know some other folks did. The SCCS is very similar to CIR, very similar to RIFM, Research Institute for Fragrance Materials, all of them doing their own studies, all of them doing safety studies.

SCC does look at sensitive sub-populations and CMR information, as well. That's part of it.
cosmeticsinfo.org. This is another website. It's not just scientific information on ingredients, but also what's most commonly used in cosmetics.

It's really kind of two-parted. It's got a safety information page, so it's useful from that front, as well as an ingredient database. It tends to be a little more user friendly for consumers because it's not total geek speak. It's dialed back a little bit so they can understand it and it sets out how cosmetics are regulated and so forth.

There's really a lot of really useful information on this site. I did get the website up there, of course, because that's what we call it. It's not very creative. We'll have to come up with a better name, I suppose, but for now, cosmeticsinfo.org. And it includes CIR summaries and other things like that. So there are other things that are out there.

My conclusions. Cosmetics are regulated. Cosmetics are safe. We believe that they are safe. I hope that you do, too. Industry responsibility with FDA oversight and third-party reviews has proven to be an effective type -- to be very effective.

We see this in the limited number of adverse event reports. Yes, I know that it's not a perfect system, as I said before, but it's the one we have and hopefully it will be improved. And consumer safety -- I know a lot of times
people say, well, it's industry, they're going to take the
lowest common denominator and they don't care about, the
consumers. They only care about their money and so forth.

Well, that's like saying, NGOs only care about
raising money and scaring people. That's not true either.
We need to have better discussions about this. But the
number one priority, of course, is the consumers, and we
wouldn't have them very long as consumers or customers if we
were harming them. We are very cautious about that. And
that's it. Thank you.

MS. RUBIN: We've got about looks like eight
minutes to take any comments or questions to Tom's
presentation. Susan.

MS. LITTLE: Sure. Just in terms of the
industry's industry initiatives, are they planning to look
into the issue of chronic effects of the products, versus
just adverse?

MR. MYERS: The chronic effects --

MS. RUBIN: Will you repeat the question for the
people on the line?

MR. MYERS: Oh, do you want -- or do you want me
to?

MS. RUBIN: It's up to you.

MR. MYERS: Do the industry initiatives look at
chronic effects --
MS. LITTLE: Relative to the long-term application.

MR. MYERS: Well, certainly. If there are reports in the published literature that look at that, then that is considered by CIR as part of their assessment. I mean, to that extent, does that answer your question?

MS. LITTLE: Just to the extent that it's actually reported, again. You don't look proactively at the potential long-term effects?

MR. MYERS: No, not proactively if it's not in the published literature. I think RIFM is different. I think RIFM actually has -- that's the Research Institute for Fragrance Materials -- they actually have scientists and actually conduct studies, as well, rather than just looking at the existing literature base.

MS. RUBIN: I'm not sure who was first. In the back? Oh.

DR. SINGLA: Veena Singla, with Natural Resources Defense Council. Thank you for a very informative presentation. I've looked at the CIR reviews before. They're very useful. My question is actually about CIR. You mentioned that they can make different findings.

If CIR finds that an ingredient or use is unsafe, then what's the process for removing that used ingredient and how is that insured?
MR. MYERS: They don't have a -- it's not an enforcement -- there's no enforcement mechanism for CIR.

MS. RUBIN: Can you repeat the question before you answer it?

MR. MYERS: Oh, yeah. Sorry. I always forget that.

MS. RUBIN: That's okay. That's okay.

MR. MYERS: The question was, is there, with regard to CIR, is there some type of enforcement mechanism? If they find an ingredient unsafe, for example, how do they go about making sure that it gets off the market and out of products? They don't.

There's not an enforcement mechanism, but when they make these findings, industry is very in tune and takes them very seriously. And therefore, if there is an -- I don't know any company, if there is an unsafe finding for a cosmetic that that industry, or there is a company that is still using that chemical as a result.

DR. SINGLA: Sorry. Just a quick follow-up to that.

MR. MYERS: Sure.

DR. SINGLA: Just I guess my concern is exactly on that point, because I know CIR did make a finding in 2011 about formaldehyde in hair straightening products, and far as we can tell there are still products with that ingredient
MR. MYERS: I'm not saying everybody's listening to us. I'm just saying --

DR. SINGLA: No. I think --

MR. MYERS: -- yeah.

DR. SINGLA: -- that's definitely a concern as far as the unsafe findings, and then ensuring that those products are actually not on the market anymore.

MS. RUBIN: Catherine, you were next.

MS. PORTER: Yeah. The process of safety substantiation that you mentioned, manufacturers have to do in order to be on the market. I'm wondering if you can describe what's entailed with manufacturers determining safety of a product.

MR. MYERS: My guess is that it varies somewhat by the manufacturer. You may have to talk to a manufacturer for that one.

MS. RUBIN: Her question was about how --

MR. MYERS: Oh, God. I keep forgetting that.

MS. RUBIN: It's all right. I got you. Her question is about how manufacturers determine the safety of products.

MS. PORTER: Yes.

MS. RUBIN: Yes.

MR. MYERS: And that would be that manufacturers have their own -- I don't know. There may be a manufacturer
in the house. I don't know. I won't put her on the spot, but I think that they all look at it in different ways. Is that accurate, Katherine?

MS. MONTGOMERY: Yeah. And I kind of touched upon our safety assessment process in the presentation this morning.

MS. RUBIN: All of the slide shows will be posted on our website, and we just had a comment from Katherine Montgomery and she was mentioning that the processes that they undergo as a manufacturer were mentioned earlier in her presentation. So you'll be able to refer back to that.

MR. MYERS: The steps they take for safety substantiation, right?

MS. RUBIN: Yes. We're going to go to Angie next, and then --

DR. PEREZ: I had a question about the CIR. The data, is there industry data within -- that's utilized within CIR also, or is it fairly --

MR. MYERS: Sure. Whoever's got -- well, they'll look at the -- all the available published literature out there on a chemical, regardless of whether it's industry funded or otherwise. So yes, there can be -- and there could be unpublished data, as well. A company may come and say here's some unpublished data, as well, that you can consider.
DR. PEREZ: Is that pretty common, that industry would submit data to CIR?

MR. MYERS: Yes. It happens, sure.

MS. RUBIN: We're going to take our next two questions from people who are participating remotely, and James is going to read them.

MR. JOELSON: Okay. The first question is from Simona Balan. Does the CIR produce new data on the cosmetics ingredients they assess? If not, how do they deal with data gaps?

MR. MYERS: They will make a finding, if there is insufficient data they can make that finding, but if there are data gaps after the initial review they'll put that out in their call for additional comments and say, we need additional information in these areas, hoping to get additional input from other entities and organizations.

MR. JOELSON: And the second question is from Alex Scranton. The claim is that adverse reaction reports are rare, only 4,000 in the last 13 years. It was recently reported that WEN Cosmetics received 21,000 adverse event reports on their products alone in the last four years.

Isn't it likely other companies have also received adverse event reports that have not been officially reported?

MR. MYERS: Thanks for the question Ms. Scranton.
The question was about the WEN shampoo. Is it likely that since they didn't report that others didn't report? Yes, it is possible. As I said, it is not a mandatory system.

That is something that we hope to make it through federal legislation or otherwise, and we would like to see. And in that case that is a classic example of how the system doesn't always reflect what's going on. There were 1,200 or so reports that came in regarding WEN products, complaints from consumers and so forth, and in fact the company had actually received thousands more that it did not report into the adverse event report system.

The system is not perfect. That was the subject of a congressional hearing as a matter of fact, and discussed at that time. And so that actually helped to make the case for Senator Feinstein's legislation or federal legislation, I should say.

MS. RUBIN: Okay. Thanks very much.

MR. MYERS: Okay.

MS. RUBIN: One more? Okay.

MS. ALCANTAR: This is Kathryn Alcantar, with the Center for Environmental Health and CHANGE Coalition. On this -- it's a follow-up question on the reporting issue. I know that part of the reason we're all convening here today is to discuss the particular vulnerabilities on nail products, both for consumers and workers.
And so one thing I just -- that was more of a question or a comment, but I'm curious, how those sort of reporting systems address for the fact that, at least for the workers, many of them are, as we've heard today, immigrants, non-English speaking folks who may not have the understanding of how agencies work and when to report or even just the agency to do that, right, because of where they're coming from and the different attitudes towards the government.

I'm wondering if any of the systems address something like that, because it could be that there is significant under-reporting happening because of that.

MS. RUBIN: Her comment was on barriers to reporting, based on language and knowledge of reporting systems.

MR. MYERS: And it's a well-made point, and I think that, certainly, they tried to address it, for example, with putting SDSs in Vietnamese or different languages and trying to get information out to the workers, for example.

But it is. It's an obstacle to reporting and it is not a perfect system, but it is the one we have, so. It's a well-made comment.

MS. RUBIN: Thanks very much. At this time I'm going to introduce our next speaker, Jill Ryer-Powder.
She's a Ph.D., she's the Principal at Environmental Health Decisions. Her presentation is going to be an Overview of Products Present at Nail Salons, Chemicals in the Products and Potential Exposures and Health Effects.

DR. RYER-POWDER: Good afternoon. First, I want to thank DTSC for allowing me to come and speak here, and then second, I kind of want to apologize in advance. My talk is more of an overview. I was picturing going first and giving everybody the broad picture.

If some of this sounds repetitive, again, I apologize, but hopefully, you have learned and you will re-learn. And I might in between interject some basic, how do you assess health hazard information, because I haven't heard about that yet, and maybe a little bit of risk assessment or hazard assessment 101 might be helpful to the audience.

That being said, my presentation is an overview of the products present at nail salons, chemicals in the products and the potential exposures and health effects. An overview of what I'm going to be talking about is, first, a statement of the chemical exposure and health-related issues in nail salons.

I'll talk about an overview of the chemicals used in nail salons. I'll discuss the potential routes for exposure in nail salons and present potential health effects
from exposure to the chemicals. First, a statement of the issues, and this is what I came up with.

In my practice, I do human health risk assessment. I look at the potential for health effects from exposures to chemicals. I combine both the information about inherent toxicity of chemicals and the exposures to come up with what is the actual risk.

From my perspective, a statement of the issues is there are a wide variety of chemicals that are found in nail salon products. It's really hard to establish a definitive list of the products. Many of the products are volatile organic chemicals that readily evaporate and could be present in indoor air of nail salons.

There are studies of health outcome to nail salon workers which show associations with respiratory, musculoskeletal and neuropsychological symptoms. There's other reported health effects that include irritation of the eyes, nose, throat, skin and headaches.

I wasn't able to come up with any definitive studies regarding reproductive outcomes among nail salon workers with regards to epidemiological studies like I was asking about where they have actual, here's the concentrations in the nail salons and here's the outcomes regarding reproductive system effect.

Correct me if I'm wrong, but I was not able to
come up with any. Why is it so difficult to come up with just a list of the chemicals? There's approximately 100 chemicals potentially found in nail salon products, and I got that from a citation from New Ecology.

A single nail polish can contain dozens of chemical constituents. We've heard that before. It's hard to establish a list of ingredients because, first, the ingredients vary between products and as we saw, there's a bunch of different products.

It's influenced by the character, such as the polish color, the texture, the drying time. We saw that there's metallic nail polishes, which would contain metals; whereas, some other polishes would not contain metals. The ingredients that are common now or in the past may not be used in the future.

For example, the gel polishes are all the rage now, and so you know, in the future we may not be using other nail polishes that you paint on one time and call it a day. And then chemicals not currently in use may become common again in the future. So again, hard to establish a definitive list and go off that one list to do future work.

The most common categories of products currently reported in nail salons are solvents, thinners, glues, nail polish removers, nail polishes, nail hardeners, artificial nails, and disinfectants. The potential routes of exposure
to workers and customers, and again, this is where I'm using my artistic license to diverge from what I originally had planned. In order to really understand what the potential for the risk or the health effect of a chemical, we need to understand the inherent toxicity of the chemical, and we also need to understand the exposure situation. How long is a person exposed? How frequently are they exposed, hours per day, days per year? What is the concentration in the air to which they were exposed? And this again, this is going to depend on their HVAC system, the ventilation, how close the worker or the consumer might be in contact with the actual product. So as a risk assessor, we need to figure out what are the potential routes of exposure. Let me talk a little bit about those.

First, there's inhalation and that's the breathing of chemicals that might volatilize from products or particulates that come off of products. There's the inhalation of volatile chemicals that are in product removal and product application.

And then the next one, that should be a big bullet, but there's the inhalation of particulates during removal and application of acrylic product. Those of you that might get your nails done or have seen people getting their nails done, when they're removing acrylics they have this machine that grinds along the nails and you get puffs
of acrylic and whatnot, acrylic and maybe residual polish coming off into the air, and you have the nail salon workers wearing those surgical masks that are obviously not protecting against these particulates.

Volatile and particulates are real important in the exposure aspect regarding inhalation. There's the dermal contact, and that's the actual contact with the chemicals for the workers, and the application of the products for the customers.

There's contact with removers, polishes, gels, acrylics and glues, and then somebody briefly discussed, there's the UV light from the gel-setting equipment. So I don't really know that that has been looked at, but basically, again, for those of you that might not have gotten their nails done, if they put on the gel product, the customer sticks their hand inside a UV lamp for three minutes at a time while they do the other hand, and then they keep switching.

For the consumer doing that every two weeks for 10 minutes each time, when you add it all up that could add up to some significant exposure from UV light. And then there's incidental ingestion, the hand-to-mouth contact. I love that picture. That was so perfect for that hand-to-mouth contact.

And just getting -- and this is, again, basic risk
assessment where people get chemicals on their hands. They
pick up their cup of coffee, drink their coffee and then
touch their mouth. And they can have incidental ingestion
from that, and any kind of hand to mouth contact, eating a
sandwich or eating a cookie or whatnot where they have
chemicals on their hands. Then there's accidental splashing.
If you look at the bottom, doing the toes there, there's
some accidental splashing that goes on where you could get
some incidental ingestion of these chemicals. I'm not going
to go through these in painstaking detail.

My understanding is my slides will be available on
the website, but I've come up with a list in those different
categories of products that I described before that look at,
what is the chemical, what might be a short-term effect, for
example, headache, dizziness, nausea, irritation, and what
might be a long-term effect.

If you're exposed to them chronically, like a
worker might be, what might a chronic effect be? And again,
I want to qualify that these are for individual chemicals.
We're not really sure what happens when you get the mixtures
of chemicals, but these are well-documented effects of each
chemical.

For the solvents, thinners, glues, nail polish
removers there's chemicals such as acetone, butyl acetate,
isopropyl acetate, methyl ethyl ketone and toluene. For the
nail polishes, there's been benzene detected in nail polish, dibutyl phthalate, butyl acetate, diethylhexyl phthalate.

For the nail hardeners, here are the chemicals associated with the nail hardeners. And then the disinfectants, which somebody discussed at the end, where the worker's required to clean out the pedicure tub each time. Those disinfectants obviously also contain chemicals and those chemicals can have potential health effects.

I put together a slide of a summary of the common effects so I wouldn't have to read through each effect. In the short term, there's irritation of the eyes, nose, throat, skin and respiratory tract; reversible central nervous system effects such as headaches, dizziness and drowsiness, difficulty breathing, and methemoglobinemia, which is difficulty in carrying oxygen to the tissues.

And then for the long-term effects there's skin sensitization, adverse effects on the liver and kidney. There's a risk of certain cancers, potential reproductive system effects and potential effects on the developing fetus. For some final comments, some types of chemicals found in nail salon products are associated with adverse health effects at certain exposure levels.

And again, we need to qualify what those levels might be and what the mixture of chemicals might be and the levels of those mixtures of chemicals. Nail salon workers
and clients may be at risk for such adverse health effects. To assess the potential for adverse health effects, it's necessary to understand the dose to which the worker or the clients may be exposed.

And then measures to decrease exposure, including ventilation, gloves, alternative chemicals, will decrease the potential for health risk. And I had a couple of thoughts when I was sitting there listening, and as a consultant I'm always interested in what can you do right now, without even having a full understanding of what's going on.

And I was thinking maybe as part of the training, these people have -- they have to get a license, obviously, to work at a nail salon, and I'm wondering if it could be part of the training, a personal protective section on, here's how you can protect yourself against inhalation of particulates, here's the reason why you need to wear gloves, and if you decrease the exposure then you're going to consequently decrease the health effects.

I am going to close with that. Hopefully, you got something out of my talk and it wasn't all repetition, and I'm glad to take any kind of questions.

MS. RUBIN: Doug.

MR. SCHOON: Doug Schoon, Professional Beauty Association. I very much enjoyed your presentation.
DR. RYER-POWDER: Oh, thank you.

MR. SCHOON: Thank you for that. I totally agree with your assessment about the training. I think training is critical to solving these issues. I heard several times people say that UV hasn't been studied, UV lights haven't been studied.

And there are actually two very good studies done on that, one by Dr. Robert Slater and John Daly (phonetic), who are world leading photo biologists who study these lamps; another one out of Brown University. If anyone wants references to these articles, I'd be happy to share them with you, because the news is very good.

They found these lamps are far safer than people imagine, largely because of the limited ranges of UV that are used. They're UVA to visible. They cut out even the low end of the UV range and focused just on the ones nearest to the visible range.

And I wanted to ask two questions after I made those comments. What do you think about, rather than using the doctor's type surgical mask, using an N95 dust mask, for inhalation of dust? And, I wanted to find out what you think would be a good alternative to doing epidemiology that doesn't involve self-assessments? Because, as we all know, self-assessments can be notoriously inaccurate, and I think we need to get some better information than simply asking
people. What do you think, without correlating it with other types of information?

DR. RYER-POWDER: Okay. The first question again was an industrial hygiene-related question, and I'm not an industrial hygienist, but I think it's a really good idea if we -- let me first repeat the question.

And, for the court reporter, and to get this on record. First of all, he liked my talk. So that was good. (Laughter)

MR. SCHOON: Very much.

DR. RYER-POWDER: Very much. And the gentleman was talking about, I had mentioned exposures from the UV light during the gel acrylic manicure, and he was talking about that there's actual studies that have been done by two separate groups showing that the health effects from those exposures are not as bad as we might think, due to the limited UV range to which people are exposed.

MR. SCHOON: In addition to light.

DR. RYER-POWDER: And then he asked me, first, if I thought that as an alternative to the surgical masks that we see the nail workers wearing, if a particular kind of mask would be more helpful to prevent the particular exposure?

MR. SCHOON: Correct.

DR. RYER-POWDER: Is that right? And I responded,
I'm not an industrial hygienist. So I can't really answer that question, but I would think as a part of the training aspect, that would be yes, these are the types of masks you would wear for those applications.

And then I am wondering from the woman who was from Coty, do you know when they do the safety assessments, is part of those safety assessments personal protective equipment and how to prevent exposures?

MS. MONTGOMERY: They're looking at the actual finished goods, if they have recommendations on how it should be applied or if there should be certain additional steps taken from the personal protection, if they would make reference to that. But it's not something that we generally always reference.

DR. RYER-POWDER: What was the next question, please?

MR. SCHOON: It was about how we can improve the value of self-assessments, because relying simply on self-assessments I think could be very misleading and has misled people in the past.

DR. RYER-POWDER: That's a tough one. The only thing I can think of off the top of my head would be if someone were to go into the community to the doctors of the women, of that specific population and somehow get permission to talk to the doctors and say, what kind of
health effects are you seeing from these types of workers, because they would have actual medical records and see, we see respiratory infections this often, we see miscarriages or whatnot.

So that's the only thing I can think of with regard to that. And then the other -- well, the other part of that if is -- I would think if you get the workers interested enough, not to the point where you're scaring them, that you might get better information from them instead of just, here's a survey, fill it out.

MS. RUBIN: So Angie was next and then Veena.

DR. PEREZ: Oh. I was just adding a follow-up question with respect to the N95 masks. Has anybody ever done a study characterizing the particle size distribution for dust or particulate emanating during a process, because I don't know if I've ever seen that, because that would really dictate what type of protection we would want.

DR. PEREZ: Does anybody know. This is to the group, I guess.

MR. SCHOON: I have done studies, but they've not been published. But I do agree, I think that's something that should be looked at.

DR. PEREZ: So N95 mask --

MR. SCHOON: N95 masks are arguably highly effective. I think one no one would say they're
ineffective, but some would be concerned that if they're not properly fitted that they might not get very good protection. It goes back to training.

DR. RYER-POWDER: The question, and the answer to the question in summary, was with regards to the N95 mask is there data out there to show what the sizes of the particles are, such that that type of mask would actually protect against inhalation of those particles.

And the answer was, there's some data out there, but not really a huge amount. Is that --

MR. SCHOON: I think that's fair to say.

DR. RYER-POWDER: Yeah.

MS. RUBIN: We're going to go to Veena and then Catherine and then -- did you have a comment or? And then Catherine.

DR. SINGLA: Thank you. Veena Singla, with the Natural Resources Defense Council. Thank you for a very informative presentation. I had kind of a comment which leads into my question. The discussion of the N95 masks is interesting, and it just made me think about my time in the lab as a grad student and when I had to wear one of those while I was working and how uncomfortable it was after just an hour or two.

I just feel like realistically, on the grounds that it would be difficult to wear all day, I just couldn't
imagine doing it. And that would lead me to my next question which -- I appreciated how you explained thinking about risk, there's inherent hazard and there's exposure. And we've talked a bit about the exposure component. I wondered if you could discuss more the thinking on hazard reduction. And, as I understand it, in the occupational hierarchy of controls, the exposure control is the last thing you want to do and you want to think more towards the inherent hazard. I wondered if you could speak to that.

DR. RYER-POWDER: I'm not sure if I agree with the exposure is the last level of control. Because the way I look at it is, first of all, I think this industry is here to stay. I think women are going to get their nails done and people are going to work in nail salons.

The toxicity of the chemicals that are used, the nature of the beast, the toxicity, it is what it is. You can't really change that unless people can find alternative products that are going to give the same quality. It's my opinion that your best defense is decreasing the exposure, and looking at ways to do so.

With regards to the mask and the acrylics, these workers aren't doing the acrylics and the grinding all day. That's limited to a six-minute deal for each customer. [The dust mask] that's not such a bad alternative.

In looking at ventilation, in looking at masks, and looking
at gloves, I think exposure reduction is our best bet for reducing the potential for health risks.

MS. RUBIN: We're going to go to Catherine, please.

MS. PORTER: Yes. Just speaking to the issue of personal protective equipment, which we, at the Collaborative, think that as much as possible should be done to protect oneself, but I just want to echo some of the things that Veena was referring to with the N95 masks. We've also had experience that they're ill-fitting, and it's not because they're not properly trained. It's because they're ill-fitting, and many of these women are very small and maybe these masks don't fit properly. And then what we've seen happen is that the dust actually collects inside the mask.

And so the particulate is trapped. So there's that side and that problem with ill-fitting masks. Similarly, the gloves, we encourage people to wear gloves, on one hand; on the other hand, there is self-consciousness around gloves because the fear is that the message to the client is that, you are unsanitary, and because you are unsanitary I'm have to wear gloves.

Now, maybe some of us think, well that's dumb, why would anyone think that? But, that concern is there. So, on one hand, personal protective equipment would be helpful,
but it's more complicated and it's not as a result of insufficient training or that nail salon workers aren't trying to do the right thing.

MS. RUBIN: Did you want to respond, Jill?

DR. RYER-POWDER: Not really.

MS. RUBIN: Okay. So --

(Laughter)

MS. PORTER: Thank you.

MS. RUBIN: Okay.

MS. PORTER: I think we're in --

MS. RUBIN: Just for people on the phone, her comments were about the challenges of personal protective equipment and some of the misconceptions that people may have when they encounter workers using this equipment. It's not just training that's a challenge in this circumstance.

MS. PORTER: Right.

MS. RUBIN: Okay. We're going to go to Patrick next.

MS. PORTER: Thank you. Well done.

MS. RUBIN: Thank you.

DR. KERZIC: This is Patrick Kerzic with DTSC. We heard Tom Myers talk about the CIR safety assessment process by which they use frequency of use as a surrogate for exposure. My question for you is do you think you could perform a credible health assessment or risk assessment
using frequency of use as your exposure method, or do you
require something more quantitative?

DR. RYER-POWDER: The question is, in order to try
and understand the potential for health effects, the CIR
use a frequency of use parameter in their safety
assessments. Would that be enough for someone like me to
come in and do a type of risk assessment to assess the
potential for health effects from exposure to these
products? Is that right?

DR. KERZIC: Yes.

DR. RYER-POWDER: I think, and another risk
assessor might disagree with me, I think without
epidemiological data it's a good place to start. Because
frequency of use is going to say using the product 500 times
a year, and then you could make professional judgments as to
time of use and sort of come up with an exposure parameter
that way, and then come up with your answer regarding
potential for cancer risk.

In answer to your question I think it could be
done. It might be crude and it might have limitations, but
I think it's better than nothing.

MS. RUBIN: And Susan was next.

MS. LITTLE: Just to clarify. It's my
understanding that the program has -- this is the Consumer
Products Safety Program -- has a more of a hazard focus from
the standpoint of looking at the hazard potential of chemicals and then looking at solutions based on that. And that's correct, right? Can you speak to that, Meredith?

DR. WILLIAMS: We have two criteria in the regulations. The first criteria is that we show that there is a potential for exposure to the Candidate Chemical in the product, and the second is that that exposure had the potential to contribute to or cause significant or widespread adverse impacts. It's not strictly risk. It's not strictly hazard. It's somewhere in between.

MS. LITTLE: Somewhere in between. So, a hazard is definitely a focus of part of the review and the decision-making?

DR. WILLIAMS: Right. And, if I could add one more thing?

MS. LITTLE: Yeah.

DR. WILLIAMS: Which is, we do consider the hierarchy of controls. We fundamentally believe that if you can eliminate the hazard you're going to be better off, if possible.

MS. LITTLE: Can you speak to that? I mean, you basically have said that you don't believe eliminating the hazard is the right approach, but instead eliminating the risk is the approach. Is that right?

DR. RYER-POWDER: I don't think she's saying that;
that's their focus to eliminate the hazard. I think we're on the same page. I think we're both saying that you need to look at the hazard and the exposure, but my opinion is that you can't change the inherent toxicity of the chemical.

DR. WILLIAMS: The purpose of the green chemistry law is to spur innovation. And so ultimately, if by taking an action we can actually initiate the search for safer alternatives, we've been successful.

DR. RYER-POWDER: Right. And again, I think that's consistent with what I'm saying. If you cannot decrease the exposure to the point where you take away, the potential for harm from the hazard, then that's incentive to come up with an alternative.

MS. RUBIN: We're going to have to stop there and move on to our next presenter.

DR. RYER-POWDER: Thank you.

MS. RUBIN: Thank you so much, Jill. Our next presenter is Paula Johnson, Ph.D. and MPH. She's the Program Lead for the California Department of Public Health. Her presentation is called California State Cosmetics Program Focus on Nail Products.

DR. JOHNSON: Good afternoon, everyone. Thanks for having me here today. We're almost to the afternoon break, so hang in there with me. I want to take this opportunity to introduce the program and give a brief update
on what we're working on that's relevant to today's workshop on nail products.

The California Safe Cosmetics Act established the Safe Cosmetics Program at the State Department of Public Health, and it's based on right-to-know, and cosmetics companies are required to report products with ingredients that are known or suspected carcinogens or developmental or reproductive toxicants, as determined by authoritative bodies.

Similar to DTSC's Candidate Chemicals list -- they have 23 lists -- we actually only reference five different lists. The Act takes a precautionary approach, not risk-based, and this means that it concerns whether or not a certain chemical is present in the product rather than the amount or how a person may be exposed.

And the intent of the Safe Cosmetics Act was to encourage substitution with less hazardous alternatives. And then also, the Department of Public Health has additional authority to collect additional information that is not subject to the routine reporting by companies.

Routine reporting is done by cosmetics companies themselves via our online system, and this is a screen shot of our public searchable database. The data is reported by companies is and then the product and ingredient information is available on our public searchable database.
You can type in, for example, a type of product like nail polish or you can type in a particular brand you might be interested in to see if it shows up on our database for those hazardous ingredients that are reportable, or you can put in a chemical name and learn more about that chemical.

And, if you would like to learn more about what's been reported to our program, we just published a report, the first report of the program that summarizes this data that was reported to the program since reporting began in 2009. And this report is now posted online and I've provided the link within this presentation, and which should be available to you after this workshop. Additionally, if you talk to me today, I'd be happy to email the link to you directly.

I wanted to just provide a snapshot of what's currently in our database for nail products. Nail products is the second largest category in our database, second to makeup. And these numbers on the screen now represent products that are presumably actively marketed. Products that have been reported to be discontinued are not counted in this table. There were a number of products that contained dibutyl phthalate, but were later marked as discontinued. I just wanted to mention that.

I also noted that the number of products
containing toluene and formaldehyde haven't changed; none of
them have been reported to be discontinued. So as you can
see here, there are a few products that are still showing up
for toluene, formaldehyde, and DBP, along with these other
chemicals. I just wanted to mention those because we've
been talking today about the toxic trio chemicals.

We do rely on companies to accurately report their
products and to subsequently make changes accordingly. One
of the limitations of the database is that if a company
edits the product report online, for example, to remove a
certain chemical, we don't see what replaced that chemical
unless that new chemical is also reportable by the law.

And then likewise, in the marketplace when certain
ingredients are phased out, for example the toxic trio
chemicals, we don't always know what is replacing them. So
due to limitations in routine reporting and because there's
plenty of interesting topics to study, we've initiated a
data call-in to some nail product companies to more deeply
examine various types of formulations of nail products.

And this includes looking at product labels, of
course, and safety day sheets, but also, detailed
formulations, which we are obligated to keep confidential at
the Health Department. And so something that is of interest
is to compare regular or traditional nail polish
formulations with the newer gel polishes, and these gels are
marketed as improvements for a variety of reasons, mostly performance reasons, but they're also considered to be odorless or less smelly.

And we want to look at this more deeply and determine if the low odor or low solvent, lower VOCs, volatile organic compound gels are of less concern, or they have other concerns associated with them. And we do realize that it's important to consider companion products, in other words, products that are used together, for example, primers that are used in conjunction with gel polishes.

And so, I'm working with the Health Department's Indoor Air Quality Laboratory and we've just begun this endeavor. Unfortunately, I don't have quantitative results to share, but I can share our plans and where we are in the process right now. One aspect of this project is to measure emissions from products, which is relevant to nail salon workers, in particular, who have potentially high inhalation exposures to nail products. But we'll keep in mind that volatile emissions are only one exposure route. And we plan to start with nail polish comparisons, but also look at acrylic and gel artificial nail systems.

As you can imagine, studying nail products is very complicated. There's a lot of different types. There's a lot of different formulations. And so far we've compiled about 120 unique formulations, which have 222 unique
chemicals. If you exclude the colorants, which are subject
to some regulation or approval at FDA, that leaves 153
different, unique ingredients. And so right now, we're
still compiling these ingredients and we're sorting through
them and we're trying to make some sense of it and
categorize the ingredients for different product types and
look at some commonalities among the types of products. For
example, some ingredients can be common between both
traditional and gel formulations, such as plasticizers. I
want to emphasize that we've really just started this effort
and it's going to rely on some cooperation from
manufacturers of nail products, and we really appreciate the
cooperation that we're receiving so far in a lot of
companies being forthcoming with their formulations, knowing
that we have to keep those confidential.

Suggestions are definitely welcome at this stage,
such as existing data or important considerations in this
study. And that's my contact information for you if you
want to provide any help with this. That's all I have.

Questions.

MS. RUBIN: Thanks, Paula. We’ve got about
ten minutes before our next break. We’re going to
take any questions or comments for Paula.

Catherine.

MS. PORTER: I just wanted to confirm,
Paula, so you said that your database shows 153 different chemicals in nail products on your database, so all those are reproductive or developmental toxicants or carcinogens. Did I understand that correctly?

DR. JOHNSON: No, no.

MS. PORTER: Oh, okay.

DR. JOHNSON: That’s a separate thing.

MS. PORTER: Oh. Sorry.

DR. JOHNSON: So Catherine’s question was: when I had mentioned that there are 153 unique chemicals in the nail product formulations that we’re looking at, if those are the ones that are on our database of routine reporting for carcinogenic or reproductive and developmental toxicants, and that’s not true, those are two separate things.

The 153 are other chemicals; that’s using our ability to do studies outside of just what’s reportable in the routine database.

MS. PORTER: Okay.

MS. RUBIN: Veena was next.

DR. SINGLA: Veena Singla. Thank you for a great presentation, and I thought it was really interesting that you’re doing a data call-in of companies and getting information. I feel like that
might be really useful to DTSC if they’re thinking about chemicals in nail products. Will you be able to share some of that information with them?

DR. JOHNSON: Well, not really, because as I said, at the Health Department we are obligated to keep the formulations that are shared with us by companies confidential. The results of any study that might include aggregated data that doesn’t identify specific companies is definitely something that is a potential to share.

MS. RUBIN: For those of you on the phone who might not have heard the question, it was about whether CDPH might be able to share the information they’re gathering from manufacturing companies with DTSC.

Doug.

MR. SCHOON: Doug Schoon. Not being a manufacturer, I’ve never had to fill out your form, so I was curious when I saw your reports of crystalline silica, which to my knowledge is not used in our industry, amorphous silica is used. I’m wondering were both asked and some reported crystalline and some were amorphous and could that have just been an error these people might not have understood?
DR. JOHNSON: I think your question is whether or not that we required reporting of both crystalline and amorphous silica?

MR. SCHOON: Correct, because it specified crystalline silica.

DR. JOHNSON: I think it does. Let me just go back to that slide, but I think that it’s listed here, crystalline, yeah, airborne particles of respirable size.

MR. SCHOON: To my knowledge our industry focuses and uses exclusively amorphous. I could be wrong, but that was just my understanding.

DR. JOHNSON: So your understand is --

MR. SCHOON: Our industry focuses on using amorphous silica, not the crystalline form, so that’s why I was a bit surprised to see that.

DR. JOHNSON: You were surprised to see crystalline silica show up in our database.

MR. SCHOON: Yes.

DR. JOHNSON: I don’t really have an answer for why that would be showing up in our database because our data is reported by companies, so you could be right, that it was a misunderstanding of what is required to be reported.

MS. RUBIN: We’re going to go to Ephrem and
then to --

MS. MONTGOMERY: I was just going to clarify.

MS. RUBIN: Okay.

MS. MONTGOMERY: If I remember correctly, you enter by CAS number. So if the CAS number is slightly off or the raw material supplier provided you the wrong CAS number, it’s very easy to get the wrong material to come up. And if someone’s not paying attention, it’s very quickly easily to be, oh, I’m using the wrong code. If I remember correctly, you enter it by CAS number and not by raw material.

DR. JOHNSON: Yes, we do have CAS number entries.

MS. RUBIN: Katherine from Coty was clarifying the reporting errors that could take place when companies make reports to CDPH, so it could very easily just by human error get entered incorrectly, so that might be it.

DR. JOHNSON: And thanks for those comments, because that’s something I always try to emphasize when I’m talking about our program is that we really can’t take responsibility for the data that’s reported to our program because it is company self-entry.
MS. RUBIN: We’re going to go to Ephrem.

DR. NEUWIRTH: This is Efrem Neuwirth. That was actually the same subject matter that I had intended to comment on was the first one when I saw that there were seven things listed there.

And I just wanted to additionally point out, since it was already addressed, was the airborne particles of respirable size, that would be the area of concern for silica but you wouldn’t necessarily know, whoever’s using probably wouldn’t know that that’s how we would classify the problematic crystalline silica.

The only study that I saw which tried to measure in a real world situation couldn’t measure at the detection on this, which was from NIOSH. I think it was a NIOSH-run study, and I think it was for the OSHA limits on silica in air, but there’s detection sensitivity issues, identifying the crystalline silica is pretty limited. You can’t get the detection level down to NIOSH thresholds; you can only get down to the OSHA standards thresholds.

I wanted to ask you more about the initial studies that you’re doing. Are they on a process where somebody’s applying the product to the nail in a way that somebody would in a nail salon or is it
just on the raw material; what sort of studies are you doing?

DR. JOHNSON: We’re starting off just within environmental chambers, small micro chambers. Sort of like a simulation, but we haven’t gotten as far as being able to simulate an entire process. These are all the chemicals for the products that you would use for this entire process, like a gel nail application. Right now we’re just we’re looking at individual products, but that is our intention.

DR. NEUWIRTH: I would follow up (inaudible).

DR. JOHNSON: Yeah, and if you have any suggestions, this is the time.

DR. NEUWIRTH: Maybe I know some people at universities that may be interested in doing some work also.

DR. JOHNSON: Yeah. Well, we could use help. Thank you.

MS. RUBIN: For those of you on the phone, Efrem’s question was about the emissions studies that they’re undergoing.

DR. JOHNSON: Just starting.

MS. RUBIN: They just begun.

Were there any more questions in the room?
Susan.

MS. LITTLE: Just a comment that it would be really helpful to get a copy of that study, or if you have any reiterations of it as you go along, it would be very helpful to see that.

DR. JOHNSON: Absolutely.

MS. RUBIN: How can people get copies of your study as it progresses, and will you be updating?

DR. JOHNSON: Well, it’s probably not going to be a state report, and, if it’s published, it would be in a peer review journal. We don’t have dissemination plans yet, we’re still in the initial stages, but I would imagine we would publish it and let our stakeholders know that it’s out there.

MS. LITTLE: (Inaudible) right now?

DR. JOHNSON: You’re talking about the --

MS. LITTLE: The study, the specific report that you’re talking about.

DR. JOHNSON: So if you’re referring to I said that we have this report?

MS. LITTLE: The one that you have right there.

DR. JOHNSON: This is the report that we just published online that summarizes all of the data.
that’s been reported by companies to our program, and
that is now available online at this link.

MS. RUBIN: Any more questions before we
take a break? Yes.

DR. SCIULLO: Yes. Eric Sciullo, DTSC. You
mentioned that your list operates off of five
authoritative lists as opposed to our 23, I believe.
Are they listed in this report? I don't remember
seeing them listed. What are the five sources?

DR. JOHNSON: Yes. And so again, this
report that’s on the screen now, it’s just published
online so you may not have seen it yet, but it does
detail what those sources are.

DR. SCIULLO: Okay.

DR. JOHNSON: And I believe my associate Amy
is here, maybe you can help me answer this. But I
think that we have that also as a regular posting up
on our database, which I admit is not organized very
well.

DR. SCIULLO: No, that’s all right.

DR. JOHNSON: It’s a typical government
database, but the sources are Proposition 65, IARC,
National Toxicology Program report on Carcinogens,
and also their OHAT, Office of Health Assessment and
Translation Reproductive Toxicant List, and the fifth
is U.S. EPA’s carcinogen list.

DR. SCIULLO: And a second part. Obviously there are requirements involved in industry having to deliver this information to you, right? I believe it has to have over a million dollars in sales, right, as part of it?

Do you have any idea of what percentage of the industry at large would you say is contributing to your report? I mean, is it 40 percent of the cosmetic industry that fits within that category of compulsory reporting?

DR. JOHNSON: The question is: if we have a sense of what percentage of the industry is actually reporting to us, right? And you also mentioned that we do have that, a million dollar annual sales as a bar to reach in order to have to be reporting to us.

It’s a good question and we don’t know how to assess that really, and if anyone has any information or suggestions of how to assess that. But we have been asked that before, how many companies are reporting that should be reporting. I mean, we know how many companies are reporting, 500 or so, but we don’t know what the universe of cosmetics really is, there’s no comprehensive list.

The FDA has a voluntary list, but then
again, it’s not really that helpful to compare who’s reporting to us those companies to their voluntary list because there’s no indication of whether those companies on FDA’s voluntary reporting system are using chemicals that would be reportable to us, so we really have not assessed that. That’s a good question.

MS. RUBIN: Thank you so much, Paula.

DR. JOHNSON: Thank you.

MS. RUBIN: We’re going to take a break and I’ll ask to you return a minute or two before 3, this is a quick break, so try to be back on time. We have three speakers left.

(Off the record 2:53 pm to 2:59 pm)

MS. RUBIN: We’re running a little bit late, so I’m going to ask you all to take your seats at this time. Thank you. Thanks for hanging in there.

We’re going to get started with our next presenter, Angie Perez. She’s a PhD, the supervising scientist at Cardo ChemRisk, and her presentation is The Screening Level Human Health Risk Assessment of Toluene Dibutyl Phthalate in Nail Lacquers.

DR. PEREZ: Thank you very much, and thank you to the DTSC for hosting us in this very informative and fun public forum.
I’m Angie Perez. I am a consultant at Cardo ChemRisk, been there for about eight years.

Just a little bit about me.

I have a PhD in toxicology. I do some testifying and then also consulting toxicology work. I’m a mom and also a foster parent licensed in California.

Today I’m going to talk about a study that we published a couple years ago with my co-author Luda Kopelovich, who you’ve heard speak today also.

We utilized the data that was published by the Cal EPA, in their 2012 report. We took that data through a screening level risk assessment, human health risk assessment, because we wanted to know: with these bulk concentrations is there a way that we could potentially try to estimate risk without having air concentrations, without having actual measured data in humans, as a preliminary first pass type of assessment. And, in full disclosure, this study was funded entirely by Cardo ChemRisk.

I’m going to skip over there because we’re heard about them ad nauseum today. The study focuses on toluene. The important point to remember here, and you’ll see it again later, toluene has a maximum allowable dose level that’s listed under Proposition
65, and that dose level, that’s for reproductive or
developmental effects, and that dose level is 7,000
micrograms per day.

Similarly, dibutyl phthalate, or DBP as its
referred to in this presentation, it also has an MADL
set at 8.7 micrograms per day.

And we’ll talk about how these MADLs are
used in the screening level risk assessment and some
pitfalls of using an MADL in this type of analysis.

This is the information that was recorded in
the 2012 report by the Cal EPA. They had three
objectives: to verify the legitimacy of the toxic
trio related products claims; number two, to
determine a baseline concentration of these
chemicals; and then also to explore the trends of
possible ingredient substitution.

Here’s a brief overview of what the sample
breakdown looked like. Predominantly, it was nail
lacquer, the actual color, nail color polish. There
were some base coats, thinners, some art. In total,
there were 25 total products sampled. They
represented 15 manufacturers. They had approximately
92 percent detection frequency for toluene, and they
had 40 percent detection frequency for dibutyl
phthalate.
They also categorized these samples by “free of” claims which we’ve heard a lot about today so I won’t go into it, but the majority of samples had no claims at all but there were some who had claimed either two free or one free.

Here’s a general breakdown of the frequency distribution of the concentrations in these products that the Cal EPA measured. You can see that the majority of the products were less than 50,000 milligrams per kilogram toluene. In fact, the median was around 6,600 part per million. We did see a maximum value of 190,000 part per million.

Now, some of the risks of the “free of” labeling are shown here, and we’ve talked about these already. For example, two products that claimed to be three-free actually had about 17 percent toluene in there. Another one had about 7 percent toluene.

There were two non-detects in the study. There were five with trace concentrations, or less than one percent, and there were five that contained toluene at greater than one percent.

Now, one thing that should be pointed out here for the study is that we were not able to ascertain the detection limits for all of the samples. Those were not listed in the study. We did
contact the Cal EPA on various occasions and were not able to, and we also contacted the lab that Cal EPA used, and were not able to acquire those detection limits. And, as such, this screening level risk assessment only includes detected samples. We already assumed an overestimation because we only included detectable samples because that value wasn’t listed.

In our study objectives we did utilize this Cal EPA data and the objectives were to quantify toluene and DBP exposures from normal use of nail products, and we did this for three different scenarios:

For consumers. The first consumer is somebody who goes into a salon, sits down and has a manicure. A home user, who was someone whom we assumed went into their bathroom -- we actually quantified the area into a small space -- they were in their bathroom painting their nails. And then, for a nail technician who conducted 16 manicures per day, so one manicure every 30 minutes. And then we took this through a screening level risk assessment.

To estimate our human health exposures we utilized the AIHA model, it’s called IH MOD, and what IH MOD is is essentially a model that you can use,
it’s listed on the EPA’s guidance list for available
models to estimate inhalation exposures, and one of
the things that it does is it measures, you can
estimate a near field and a far field. What a near
field is: if you hold your arms out imagine a sphere
around your head with you just holding your arms out.
And a far field is the size of the room minus your
near field bubble, that’s how you calculate a far
field.

What we were trying to get at is, if I’m
getting my nails done, I’m also experiencing the same
exposures that Eric and Christine and André might be
experiencing also. We summed up all of those
different exposures this way.

And then for the well-mixed room model, we
assumed that this was only consumer use and then we
assumed this was a pretty small test, like we’ve
said.

For dermal exposure we utilized again the
AIHA model SkinPerm. SkinPerm is used by the
equivalent of the French Food and Drug
Administration, ANTES, so they utilize and publish
reports using the SkinPerm model, so it’s something
that is widely available and used. Essentially it
uses some quantitative structural activity
relationship methodology to estimate a skin
permeability specific to each chemical.

We did this for both DBP and toluene, and
the results are as follows.

Just to give a brief overview of our
exposure too. If you are a salon patron, we assume
that you have one manicure a day. That’s a lot. I
mean, nobody’s going to get a manicure every day.
And that’s important because of some earlier comments
about the CIR database where we were talking about
frequency.

With proper frequency information you can
actually calculate a more realistic exposure
scenario. And not only is that important to get a
more accurate representation, but it also can, in
this case, be important for Prop 65 claims because --
and I wish Tom was here because he probably knows
more about it. But, the Beechnut decision was one
that happened about two years ago where consumers of
fruit juice that had detectable lead were concerned
about exceeding the MADL for lead under Proposition
65. And because Beechnut Corporation had really
reliable data on the frequency of consumption of
their product, they were actually able to average
that exposure out over every seven days. They knew
that people on average drink one of their drinks or
had one of their products every seven days, and so
with that information they were able to average that
exposure out.

Versus me saying I’m assuming your exposure
is X because you get one manicure every day, and
that’s important, that’s pretty important.

We assumed it took 30 minutes for you to
finish your manicure, and we also assumed you had
three other patrons in the salon with you.

For the home user we assumed you also had
one manicure a day and that your manicure lasted 60
minutes. And then we also assumed that you were far
more sloppy with your application -- which I don't
know about for you but for me that’s absolutely true
-- so with your application we assumed a larger
surface area. We assumed that you actually spread
fingernail polish on the total surface of about three
tips of each finger, so it’s a gross overestimation.

For the nail technician worker, we assumed
you did 16 manicures each day, each was 30 minutes in
duration, and that there were three other technicians
working in the salon with you.

The results of the study are as follows.

I’m showing toluene estimated air
concentrations using the IH MOD for the near field and far field, and the two zone model represents the cumulative near field/far field. If I add my exposure and then I add all three of yours together, that’s what that value represents for the two zone model.

And what I’m showing here is that the majority of the samples were far below the OSHA PEL, so it’s not showing, in this case, to be a risk for workers using this exposure scenario. And it’s also below the Cal OSHA PEL of 10 ppm.

What we did see, though, was an exceedance of the U.S. EPA reference concentration, and that’s a concentration you can have every day all day long without having an increased risk of disease or adverse effect. We did see some exceedances with the RFC only for the maximum concentrations.

Similar results for the well-mixed model.

That’s where you go into your bathroom and you paint your own nails. Majority of the samples were less than the U.S. EPA reference concentration but there were a few that exceeded.

Now, if we think about cumulative toluene exposure, this is taking into account not only inhalation but dermal exposures to toluene also, what
we see is for a technician, we exceed the Proposition 65 MADL of 7,000 micrograms per day; in fact, by quite a bit.

We don’t see any exceedances with the patron, but we see an exceedance of the maximum value with the home user.

Now, I want to preface these results by saying that this is assuming you’re getting a manicure every single day, so this is an overestimation. So for this day you would exceed under these parameters, but if it’s only once every certain amount of time a home user probably wouldn’t exceed.

So DBP, dibutyl phthalate for dermal exposure, this is again using the AIHA model for SkiPerm. We again saw exceedances in all scenarios.

I also want to preface this by saying that, just for fun, there was one limit of detection that the lab provided us; they said it was their average limit of detection, but since we didn’t have it for all the individual samples we didn’t use it. But, if you run the limit of detection, which I think was 4,700 ppm through that lab, you actually exceed the MADL if you back calculate.

So, therein, is the issue with using MADL
and comparing against MADLs, because the concentration that would need to be present of DBP that would need to be present in a lacquer would have to be below 6 ppm, so that’s 700 times less than the lowest detection limit reported by the lab that the EPA used.

We all understand that MADLs have a thousand-fold uncertainty factor. And my point in my discussion in this room today, too, is how relevant is this as a benchmark to compare against in terms of really getting at human health risk, trying to understand human health risk.

To conclude, we agree that product labels may not accurately represent true content. We only saw only the polish with the maximum toluene concentration resulted in exceedance of the MADL for technicians and for home users.

And then we typically, just to put a number on it, only polishes with toluene concentrations greater than about 13 percent exceeded the RFC, the reference concentration in our scenarios.

The MADL for DBP was exceeded in every scenario, even in those below detection limit; so, clearly there is a disconnect between the detection limits and the MADL for DBP. And then, also
exceedances of an MADL don’t necessarily indicate risk, particularly in this scenario.

I put this on here. I’m so glad we were talking about ventilation too because I was trolling the internet and found this really cool ventilation device, and I was hoping that one of the industry representatives might speak to it.

But as Veena pointed out, it is uncomfortable. I’ve worn facemasks, I’ve worn a PAPR, I’ve worn full Tyvex, the whole nine yards, and they’re really uncomfortable and hot and I wouldn’t want to go to a nail salon and see somebody in full face gear. I’m hoping that with innovation they’ll find different solutions.

It’s difficult to see here but it looks like a vacuum cleaner hose that’s hooked up right next to the nail station and then it sucks it all out so you hopefully will minimize any exposures, especially to some of the particulates.

Ventilation is variable. That’s one thing that was difficult to control in this study. We assumed one air exchange per hour per the EPA Exposure Factors Handbook.

We also know that dermal exposures, in this case, are likely overestimated. We assumed one per
day. We assumed you were very messy and terrible at painting your fingernails, which may actually be reflective of a child.

We also didn’t take into account a cumulative dose, you’re getting a manicure and pedicure. And we also didn’t account for any other types of nail treatment services, any acrylics, gels. I mean, the sky is the limit on research in this area, truly.

We also didn’t account for loss of toluene. Toluene potentially will volatilize and you may see a decrease of toluene in a bottle over time.

There’s a lot of unanswered questions with this type of data. And I’d love to answer any questions.

MS. RUBIN: Thanks, Angie.

We’re going to take any comments or questions right now from our participants in the room. Does anyone have a question or comment?

Patrick.

DR. KERZIC: This is Patrick Kerzic with DTSC. Thank you for making that talk, it was very nice.

There are methods by which you make extrapolations from types of exposure assessments to
determine bioavailable dose and, maybe you can find
an internal concentration that’s estimated. Have you
gone down that road? And, if you have, how does that
relate to some of the things that I’ve been seeing
with NHANES data and BiomonitoringCalifornia?

DR. PEREZ: The question was about
extrapolating from these types of exposure
assessments to determine what would be the
bioavailable dose, I’m assuming, and then how you
compare that bioavailable dose to, for example, NHANES
data, some of the biomonitoring, like urinary
metabolites or California Biomonitoring data.

No, we haven’t, but that’s a really
interesting question.

I will say that the SkinPerm model is
actually measuring what would be considered a
bioavailable dose. It’s assuming full permeability
through epidermis and dermis, and so we considered
that. And they have some language in their
guidelines about how to interpret, but it would be
considered at least an internalized dose or what we
consider to be bioavailable.

Does that answer your question?

DR. KERZIC: Yes.

MS. RUBIN: André?
MR. ALGAZI: Angie, thanks for the good talk. André Algazi again.

You mentioned the loss of toluene, which made me think about the addition of neat toluene back into the products. Did you use that in your scenario at all or just assumed that the products were as they are formulated?

DR. PEREZ: I’ve never even heard of that before today. So that was news to me that that even happened.

MS. RUBIN: Anybody else? Anyone on our webinar?

MR. JOELSON: No.

MS. RUBIN: Thanks.

At this time, we’re going to move to our next presenter, who is participating remotely. Our next presenter is Aja Frierson, founder of Habit Cosmetics, and her presentation is about Exploring the Gap Between Performance and Safety.

MS. FRIERSON: Hi everyone. It’s been great listening to some of the speakers today and I just want to say thank you for inviting me and to the DTSC for letting me participate.

MS. RUBIN: We’re ready when you are.

MS. FRIERSON: To give you an overview, My
goal for this presentation is to address some of the
questions that Dr. Sciullo raised in his presentation
last year on the toxicity of certain chemicals in
nail polish. I’m also hoping to provide a
manufacturer’s perspective to explain why they use
some of the chemicals they do, and to explore how we
can make nail polish safer, yet still have it perform
the way consumers expect.

To be clear I am at the helm of a brand that
produces nail polish, but I’m not a chemist or a
manufacturer myself. I came into the beauty industry
as a consumer that wasn’t seeing the kind of products
I wanted available in the marketplace, so I designed
a product and sourced manufacturers to make it. So
this presentation is based on conversations I’ve had
with my manufacturers as well as roughly six years of
experience being active in the beauty industry.

I’d like to give you a bit of a background
on why I started Habit.

Basically I went through a period
[interference] I was obsessed with nail polish and
began painting nails all the time. [interference]

DR. WILLIAMS: Aja, you’re breaking up a
bit, and so could you back up a little?

MS. FIERSON: Sure, I’m sorry about that.
So I just wanted to give you some background on how I started Habit. Can you hear me clearly now?

So anyway, I just wanted to give you a little background about how I started Habit.

Basically, in 2011 I was painting my nails all the time, so they started peeling because nail polish is very drying, and so I started looking for a strengthening polish to solve that problem. All I was seeing on the market were formaldehyde-based strengtheners, and I didn’t want to use formaldehyde-based strengtheners.

I try to limit my exposure to carcinogens if I can help it, so I sought out alternative strengtheners in the plant world, and I found that myrrh extract strengthens nails and it’s also antiinflammatory, antifungal, and antibacterial.

To summarize, I saw a gap in the marketplace for a nail polish with natural strengthening properties and I began development on Habit in 2011. In June of 2015, after two years of development, I launched the brand.

I try to make Habit as toxin free as possible, so to that end we work with a manufacturer in California that makes Habit free of toluene, formaldehyde, formaldehyde resin, camphor, triphenyl
phosphate, dibutyl phthalate, xylene, and parabens.

We are also launching three new products later this year and two of those products are almost completely organic. And the reason why I mention that is because creating them has taught me some interesting new things about formulation in the beauty industry that I will talk about later.

Now I’d like to talk about some of the chemicals that can be found in nail polish, and I can’t tell you to what extent these chemicals are still used by the industry as a whole, but I can give you the perspective of my nail polish manufacturer.

That being said, Habit’s manufacturer has been in business since 1993 and they’re the largest nail polish manufacturer in the United States, so I think their answers are a good indication of where the industry is at.

They discontinued the use of formaldehyde in all of their nail polishes with the exception of one nail product they sell, which is a nail hardener, and they continue to use formaldehyde in that product because they say it’s, without a doubt, the most effective nail hardener. The fact that they continue to sell that product just tells me that there’s still a market for it.
Toluene is a solvent they stopped using roughly 14 years ago.

Dibutyl phthalate was removed in 2004.

Triphenyl phosphate was removed in 2012; concerns over that have been a more recent development.

UV absorber Benzophenone was replaced with Benzophenone-1, which is made from benzene, a different molecule.

They still use silica primarily to suspend glitter in glitter polishes but also to reduce gloss in matte nail polish.

And they use titanium dioxide as a colorant.

It’s also widely used in cosmetics in general and personal care products like toothpaste, paint, plastics, and paper.

Moving on, I’d like to talk about some of the alternatives available to the Candidate Chemicals that I just mentioned.

Speaking for plasticizers like triphenyl phosphate and dibutyl phthalate, the good news is that there are literally hundreds of alternatives that can replace them. But TPP was actually initially adapted as a replacement for dibutyl phthalate so the alternatives aren’t always better.
Also replacements for DBP and TPP are more expensive. The same is true for the replacements to toluene, and manufacturers, of course, pass these higher costs on to brands, who pass those on to the consumer.

When toluene and formaldehyde resin were removed, adhesion, gloss, and polish hardness suffered, so isobutylphenoxy epoxy resin was added to regain those properties, but that ingredient is now on an EU banned and restricted fragrances list for being an immune system toxicant.

Benzophenone-1 may be an endocrine disruptor according to several studies done in the 2000’s. And there are other UV absorbers that can be used in its place, but it is unknown whether these alternatives are safer and they’re definitely more expensive.

Silica also can be replaced with Stearalkonium Hectorite; however, silica is clear whereas Stearalkonium Hectorite gives polish a muddy brown tint.

And as far as there being different formulations for salons versus those sold by large and small retailers and luxury stores, that was a question that was asked last year. Manufacturers sell the same base formulas to everyone. Of course,
there’s always the option to customize your formula, which is what we did.

Another nail polish brand that I know has a custom formula is the polish sold by Christian Dior, and I know this because my manufacturer did fillings for them. In that case, Dior delivered pre-made polish and printed bottles to my manufacturer, and all my manufacturer did in that case was machine-filled the bottles for them.

The drawback to customization from a brand perspective is that it usually comes with higher material and labor costs and higher order minimums, so because of that, my opinion is, you’re more likely to get customer formulas with higher priced nail polishes like Habit and like the nail polish sold by Dior.

Today we’ve been talking primarily brands sold in nail salons, and from what I understand, salon brands were the brands that the DTSC tested in 2012. Unless nail salons specifically market themselves as being low toxicity or “eco-friendly” or if they are marketing themselves as a luxury type of salon, then they’re likely buying the cheapest nail polish possible because most nail salons make business doing the most volume they can at any cost.
I would say that the brand whose bread and butter is selling low cost nail polishes to salons are more likely to use cheaper chemicals to keep their costs down, and toxic chemicals tend to be cheaper.

Also, if you’re a brand that wants to have the lowest cost possible, China can make almost everything cheaper than U.S. manufacturers can. Some of these brands may be making their polishes in China, and the problem I see with that is, unless you’re familiar with how China regulates its cosmetics industry and you’re confident that your manufacturer is following those regulations and you’re happy with what those regulations are, then you don’t really know what you’re getting.

There are standards and regulatory agencies that exist to guide manufacturers in formulating their nail polish, which some people addressed earlier today, and here’s a list of some of them. You can look at that in depth when this presentation is posted.

I can’t say if any of the rules are enforced or if they’re simply guidelines that my manufacturer is expected to abide by, but I can say that my manufacturer claims to follow the good manufacturing practices that are set forth by the FDA as well as
good laboratory practices set forth by the FDA and EU Council directives.

To close, I would say that the DTSC might consider adding isobutylphenoxy epoxy resin to the Candidate Chemicals list. There’s not a lot of information available on it but it is listed on an EU banned and restricted fragrances list as an immune system toxicant or allergen.

I also suggest adding formaldehyde resin to the list, as it can be derived from formaldehyde.

Also, I know the DTSC is concerned about titanium dioxide as well as some D&C colors, which I saw several of those listed in the Candidate Chemicals database, but I think it’s going to be very difficult to try and eliminate those colorants from cosmetics.

Color is one of the main reasons that people buy makeup and there are only so many colors and textures that you can get with micas, iron oxides, and animal-derived ingredients, if you’re using those, like carmine and pearl. There are alternatives in natural pigments and those can be made, for example, from cabbage, beets, and turmeric, but they can be expensive. One quote I got from a manufacturer for $1,300 per color and that’s a
minimum order, or per pigment powder, I should say. Also, these natural pigments have a very high plate count specification, which means that the amount of colony forming microorganisms per gram of powder is very high. For reference, natural pigments contain about 50,000 colony forming units per gram of powder whereas iron oxides contain about 100 colony forming units per gram. This means that if you use these colorants your products might spoil before you can sell them.

The manufacturer I spoke to about these natural pigments believes that some cosmetic companies get around this problem by irradiating the pigments, and that’s safe. All of us have probably eaten irradiated food at some point, but extra processes add to costs.

Something else to consider is that the color itself in these pigments is not very stable and can fade quickly when exposed to light.

I know from personal experience there is, based on what you found during your 2012 investigation of nail products, sometimes products are advertised as being free of certain chemicals when they’re not, and that’s why I mentioned earlier that I’m developing new products because during the
development phases I made new discoveries.

So, to tell you how things work when you’re developing new products, you do something called trend shopping, which is basically you’re trying to get good ideas from your competitors and see what they’re offering.

Though I really like the formula that one company offers, and part of what I like about it is that it was supposedly free of FD&C colors. This company’s packaging listed only iron oxides and micas as colorants, and I’m doing my best to avoid using FD&C colors in my new products. So, I bought one of their products and sent it to my manufacturer to reference.

Well, my manufacturer did some research on this company and found an ingredient listed on their website for the same product that I sent her, but this ingredient list showed FD&C colors as being a part of the formula. If an average consumer purchases this company’s product from a store, like I did, but doesn’t check the ingredient list on the company’s website, they would think they’re getting a product free of artificial colorants.

It seems like this was just a mistake in this case because at least this company had a correct
ingredient list posted somewhere, but I do believe there is some intentional obscuring of the truth going on when it comes to ingredients.

And I don't know if it happens at the brand level or at the manufacturer level, but speaking specifically of FD&C colorants again, there are several companies who advertise their products as being free of artificial colorants and yet they sell really bright colors.

Well, there’s something I’ve discovered through attempting to make new products without FD&C colors, and that is it’s impossible to produce really vibrant colors without artificial colorants.

There’s one company out there that claims to color everything with fruit pigments, and my lab has told me there’s no way they’re being transparent about what’s in their makeup. But at the company I’m speaking of they have their own lab and the founder is a chemist. Who really knows what’s going on at that company?

Ultimately, I think the burden of removing harmful chemicals from nail polish falls on the brands selling these products and on the manufacturers making them. I think, for change to occur, brands have to care about their product
ingredients and they need to work with reputable manufacturers that care about ingredients also.

But I think there is still a lot of research that needs to be done to find alternative chemicals that are non-toxic but still perform well and are not prohibitively expensive.

Does anybody have any questions?

MS. RUBIN: Thanks, Aja.

We have a few minutes to take any questions or comments. Please speak up. We only have a couple of microphones that go through to the people joining us remotely.

Doug.

MR. SCHOON: Yeah, Doug Schoon. Unless I misunderstood, it sounds like you’re advocating for cosmetic companies to use unapproved FDA colorants.

MS. FRIERSON: I’m sorry, could you repeat that?

MS. RUBIN: I’m going to repeat the question for you and everybody else participating remotely. He is asking you to clarify whether you are advocating for manufacturers to use colorants that are not FDA approved.

MS. FRIERSON: Oh. I just think it’s an alternative that can be explored and something to
I’m sorry if I was a little misleading. When I was speaking in the presentation about attempting to not use FD&C colors, I would still be using iron oxides and micas and that was for non-nail polish products but I brought that in as an example of how I feel companies aren’t totally transparent with their ingredients sometimes.

MR. SCHOON: So she does agree that all colorants need to be FDA approved.

MS. RUBIN: Yes. He’s asking if you agree that all colorants should be FDA approved.

MS. FRIERSON: Yes, I think they have to be.

MR. SCHOON: The other question I had was I noticed that you have paraben free, which parabens are preservers for water based systems and there are very few water based nail polishes, so I was wondering if you found a lot of paraben-containing nail polishes?

MS. RUBIN: (Repeats question.)

MS. FRIERSON: You know, I’m not sure about that. I just know that it’s something that our customers were concerned with having it free of paraben, so it’s something that I thought to advertise.
MR. SCHOON: But if nobody else uses parabens in their nail polishes and you say paraben-free, isn’t that semi-deceptive at least?

MS. RUBIN: (Repeats question.)

MS. FRIERSON: I think there are polishes that use parabens. I can’t say any off the top of my head.

MS. RUBIN: Okay. Anyone else?

MR. JOELSON: David Lennett asked do you have other phthalates in your products besides DBP?

MS. FRIERSON: Yes, we do. There are ingredients posted on our website in each product or in each color. Yeah, so we do use some phthalates but not DBP.

MR. JOELSON: That’s it.

MS. RUBIN: Anybody else? Yes.

MS. ALCANTAR: This is Kathryn Alcantar with CEH. You mentioned that you had the list of ingredients on your website. Does your company offer the full ingredient list on your website?

MS. FRIERSON: Yes, it’s on the website. Basically, if you pull up any individual nail polish product, the ingredients list is listed there for each color.

MS. ALCANTAR: And so my follow-up question
MS. RUBIN: (Repeats question.)

MS. FRIERSON: I would say we’re occupying a space in “green” or the “natural” beauty industry for trying to be as natural and non-toxic as possible, and I think in that sector they really value transparency. We do get comments from people that are picking apart the ingredients list and say, well, I read on EWG’s SkinDeep database that this certain ingredient is of concern, why do you guys put it in or can you take it out? And so I’ll talk with my manufacturer about whether we can take certain ingredients out.

But I think that the problem is you want to take as many toxic ingredients out as possible but at the same time you have to produce a nail polish that will meet the performance standards that people expect of a traditional nail polish.

You have these alcohol-based nail polishes and water-based nail polishes, but I don’t see those overtaking traditional nail polish because they don’t really perform like you would expect nail polish to...
do. You can’t put your hands in warm water or the
nail polish will come off. And you don’t have the
same type of colors.

MS. RUBIN: Okay, thanks Aja. Any other
questions?

MR. JOELSON: No more on the web.

MS. RUBIN: Okay. Our last presenter for
the day is Jen Jackson. Jen is the Toxics Reduction
and Healthy Ecosystem Project Manager of the San
Francisco Department for the Environment, and her
presentation is San Francisco Department of
Environment’s Nail Product Database Research Update.

MS. JACKSON: Jen Jackson. Thanks so much
to all at DTSC for having us here. I’m with the San
Francisco Department of the Environment. I oversee
the toxic reduction program, which has lots of
different programs, one of which, it’s my pleasure to
oversee, is the healthy nail salon program.

As you heard from Catherine Porter earlier,
we’re one of the five counties that has a healthy
nail salon program, and we were the first city to
start implementing one.

Within the Department of the Environment, we
have the luxury of working with the precautionary
principal ordinance, so that basically charges us
with not necessarily needing to have all of the
scientific data at our fingertips to decide to take
action if there’s a potential for harm.

We decided in 2012, as we were hearing from
the Asian Health Services, which is an organization
in Oakland, that there were a number of cases of
people having various problems, and so we thought,
you know what, we probably could take action. We
might be able to help people get ventilation units in
their salons. We may be able to help them find
alternative products that don’t have the toxic trio.
So we began the program.

And our program, just for ground truthing,
we have about 250 salons in San Francisco. As
someone mentioned earlier, it’s a very robust sector.
We are a 49 square mile city with 250 salons, so we
have a lot of salons. In our program, we have about
40 salons that are healthy nail salons.

I say that because there’s been a lot of
discussion about training and letting people know
about all of the various things like gloves and
ventilation, and this is a community that needs
serious hand holding. There are language barriers,
as we’ve heard. We need to go in every year at least
to make sure that the ventilation units themselves
have had their filters checked. These women are working day in and day out with people’s hands and feet, and it’s often a second thought, it’s not their first thought to be checking some of these things.

So we have to go in a lot, and that means that our one full-time employee who was supposed to present today and is sick, she is spending a lot of time just making sure that those that are in our program are able to comply and complete the criteria within the program.

As we’ve already heard, the chemicals that are in a lot of these products, there are so many products and these are just the polishes. We know that there are gel products, there’s the solvents, the thinners, the removers, the strengtheners, all of those things, and a lot of these use chemicals that are used in them are industrial chemicals, so we work with our Department of Public Health in San Francisco who employs industrial hygienists, and they came to us saying we’re really concerned people are using chemicals in nail salons that are being used in auto body part painting facilities. These are the same kinds of things that we see in industry, and they have no personal protective equipment. What can you all do?
This is a real fact that they’re exposed to chemicals that folks in other industries, where they’re wearing protective equipment, are exposed to. And then, of course, employee health. These are real people who are trying to make a living and we are concerned about their health.

Back in 2011 when we were approached by Asian Health Services and the Nail Salon Collaborative, we decided that the precautionary principal also asks you to look at what science exists, so we undertook a database project where we took a look at all of the ingredients that we put in various different products in salons to identify what would be the worst chemicals that would be in these salons, and so that’s really where the toxic trio for us was. We solidified the science, we understood that those were the ones we were most concerned about, so that ended up becoming part of our criteria, so when a salon becomes a healthy nail salon they have to eliminate the use of dibutyl phthalate, toluene and formaldehyde in their products.

A lot has changed in the last five years, so what we are doing now is relooking at that information. As you’ve heard, there’s been a lot of
changes.

We are seeing the advent of gel nail polishes really taking over. Traditional nail polish is definitely still used, but gel has really taken off.

And interestingly, we’re finding that, at least in our healthy nail salons they are actually trying to move out of the acrylic nails, the artificial nails, I should say. That’s a good thing that the education that we’re providing them that they’re exposed to a lot more chemicals when they do artificial nails, that’s encouraging them to move out of that service. But the gel nails are really scary to us; we’re really concerned about them.

We decided to do, in collaboration with a number of organizations whom you’ve already heard from today, so Paula from California Department of Public Health, Virginia St. Jean from our Department of Public Health in San Francisco, and Catherine Porter from Healthy Nail Salon Collaborative, and we have assembled a lot of SDSs for products from 2011 to today to see what is in these products.

As you know, and as we’ve already heard, there are a lot of problems with SDSs. They do not necessarily list all the ingredients nor are they
supposed to, but we’re just working with what people are disclosing as the problem chemicals in their products.

With traditional polishes, we basically assembled quite a number of 95 traditional nail products from 40 brands for a total of 1,042 ingredients that were disclosed on SDSs, so we put all of those into a big Excel spreadsheet to see what rose to the top.

So, 97 percent of products contained butyl acetate, 96 percent contained ethyl acetate, and you can read the rest yourselves. This isn’t necessarily any kind of smoking gun, but when we compared it against the toxic trio they didn’t really show up very much, which is great, so there’s a lot less use of the toxic trio.

But triphenyul phosphate is actually pretty high, so 32 percent of the products that we surveyed -- again, these are just products that we found in salons that we were working with and also in supply shops -- so 32 percent contained triphenyul phosphate.

And then these are the other Candidate Chemicals that are the 20 that were listed in the preparatory documents for this meeting. We
understand that there’s some 3,000 candidate 
chemicals and we would like eventually to compare our 
list with that full 3,000.

But a note on chemistry, as others have 
said, CAS numbers are not consistent. One SDS may 
say one number for a chemical and it’s another number 
in a different SDS, and then comparing that to the 
CAS number that’s in the Candidate Chemicals list 
could be a completely different number. I’m really 
excited about the website that the gentleman that 
spoke earlier talked about INCI because we’re going 
to have to take a look and see if we can try to 
compare some of these chemicals, but it’s really 
challenging. It’s tedious work as well.

With the gel polishes, these were the top 
ten ingredients that we found, and we had 47 gel 
products, 15 brands, and 771 ingredients that were 
reported on the SDSs. Again, that doesn’t include 
all the ingredients, it’s just what’s reported on the 
SDSs as potential a hazard.

So, 47 percent contained hydroxy ethyl 
methacrylate and 45 percent hydroxycylohexyl phenyl 
ketone. And again, we compared that against the 
Candidate Chemicals list and titanium dioxide was the 
highest but triphenyl phosphate was in quite a few
products.

The other thing that we found really challenging, again because of nomenclature in chemicals, there are quite a few acrylates that we found in gel polishes, and so we’re not chemists and so we’re not sure how to compare those and so we’d love to work with DTSC to try to see if there’s some way to compare that with your Candidate Chemicals list to try to group things that we’re not quite sure how to do that.

For the future, the next step is to take a look at the artificial nail products, and currently we have 33, 13 brands and 121 ingredients from SDSs and we’re hoping to get more SDSs. As someone said earlier, a lot of this is going to supply stores, asking them for an SDS, asking a nail salon if they have the SDSs on hand, or calling manufacturers or looking at their websites, so it’s hard for us to get all this information, so those in the industry that are here, we’d love to get your information, that would be great.

And we also are hopeful that in this process that for DTSC and everyone in the room that folks can really think about that this is not that we have to have a full stack of studies that show harm. If we
can move out of problem chemicals like toluene,
dibutyl phthalate, and formaldehyde, like we already
have, and other problem chemicals that we’re now
finding in these polishes and find safer
alternatives, why not? Why shouldn’t we do that? It
seems like it just makes sense.

So with that, I’ll take questions. And if I
can’t answer a question because my staff person who
implements this program and is our subject matter
expert isn’t here, I can always follow up with her
and answer those questions.

MS. RUBIN: Let’s start with Cathy.

MS. PORTER: Yeah, kind of a comment just to
add a little more context to this ingredients review.

This was started, and I think Jen mentioned
this, to take a look at what chemicals were in
products now in healthy nail salons. In healthy nail
salons they can’t use products that have toluene,
dibutyl phthalate, or formaldehyde, so the question
for us was what is replacing those three chemicals?

I don’t think we can look at this survey of
ingredients to tell the larger story of how pervasive
the toxic trio is in the whole world of nail salon
products, in cheaper nail salon products and in
retail products, because these salons by definition
should not have any products with the toxic trio. I just wanted to make sure that people got that kind of contextual setting.

MS. JACKSON: That’s a good point.

We did go into some supply stores but most of the SDSs are for products that are in our healthy nail salons, so we were trying to see what the replacement chemicals might be.

MS. RUBIN: Doug?

MR. SCHOON: Doug Schoon. I thought your final comment was interesting, that if we don’t have studies to show harm, why not remove the ingredient anyway, and I think there are a lot of reasons for that.

I think that if we don’t know that there’s harm and we don’t have reason to believe that the ingredient should be removed, then I think we should question whether or not it should be removed.

And I was very pleased today to hear the DTSC is not just going to take a hazard list approach or just the risk based approach. They’re going to combine the two and look at them. Because I think that we want to move carefully, not jump out of the frying pan into the fire, as I’m sure everyone agrees, but I think we really need to rely on studies
to determine which ingredients ought to be replaced and which ones we ought to study more.

MS. JACKSON: Do you want to repeat that?

MS. RUBIN: I’ll do my best to summarize it.

Doug was commenting on the last point that Jen made in her presentation about even if we don’t have significant data showing harm from particular chemicals, why not remove them if it’s possible. And he wanted to share that he thought studies were necessary to determine if there is harm before removing a chemical, and remarked on our plans for determining which chemicals will be considered.

MR. SCHOON: Well, modify that. I’ll just say I think we need studies as well. It shouldn’t be just because it’s on a list it should be removed. I think it’s a combination of things we look at.

MS. RUBIN: Remarking on we should be looking at a combination of things, doing studies, not just removing a chemical because it’s on a list of potential Candidate Chemicals.

MR. SCHOON: Right.

MS. JACKSON: I think I would agree in some ways. Titanium dioxide, unless it’s in a powder form, we’re not really concerned about that probably, but I think that there’s enough data for many of the
things on the Candidate Chemicals list that if there
is a safer alternative, why not, let’s move in that
direction as soon as we can and prevent harm from the
very beginning.

And, just a note about the ventilation
units, they cost about $1,500 for a salon to
purchase, which doesn’t sound like much perhaps to
anyone in this room, but salons make very, very small
margins. For them to get a ventilation unit is
pretty expensive and it’s a one-time outlay of cash
they may not have, so that’s a really big barrier to
increasing the mix of fresh air into their salons.
We also encourage to open doors, which is really easy
in San Francisco most of the year, but in a lot of
other places that’s just not possible.

In New York and other communities, they’re
starting to require a whole HVAC system. But again,
if a salon is approaching a landlord and saying I
want to put a salon here and I may have to go get
this HVAC system, they may not be able to set up
shop.

We are trying to remove some of those
barriers through our program. We’re working with the
Healthy Nail Salon Collaborative to offer micro loans
so that they can pay that off over a three year term,
I believe it is.

And then when we started our program we actually offered free to the salons so they could get going and sort of prove the concept that it would be helpful.

MR. SCHOON: You’ll be very happy to know that I know this company where the price of their units have dropped down to around $800, because I do agree with your earlier statement. I think alternatives like this are in many ways better than a huge HVAC system that might not work for a mobile technician, someone moving from place to place.

So again, I think we should look at a wide range of alternatives, and I think that’s in the spirit with what the DTSC is looking for, is innovation, and fortunately there are ventilation companies out there who are innovative.

MS. JACKSON: And I would love it if a salon is purchasing something with really toxic chemicals that they got a free unit along with it.

MS. RUBIN: That’s just a follow-up discussion on the ventilation units that Jen mentioned and just looking at different ideas and trying to come up with solutions, realistic practical solutions to ensure the safety of nail salon workers
and people who visit them.

All right. We’re going to hit Veena next and then you, Patrick.

DR. SINGLA: Veena Singla with NRDC. Thank you for an interesting presentation, and I think following up on your comment about really thinking about moving to less hazardous chemicals, I think another benefit of that is to avoid this kind of cycle of substitutions which I think we’ve seen throughout some of the various presentations and the previous one, you know, in 2002 this one was removed, 2005 that one was removed, 2012 the next one was removed.

I think really giving consideration to the health and safety characteristics of a chemical before you use it as a replacement and trying to go to a safer alternative has a lot of benefits. It’s more of a comment.

MS. RUBIN: (Repeats comment.)

MS. JACKSON: And if I can add, I think the alternatives assessment process is where we’re heading. Hopefully we do find things that won’t be regrettable substitutes for things but much better.

MS. RUBIN: Patrick.

DR. KERZIC: Patrick Kerzic from DTSC.
Regarding the ventilation units, I know with other parts of our program, we offer mitigation measures for contaminated sites that sometimes flat out don’t work. Do you know of any efforts to empirically determine the efficacy of these units?

MS. JACKSON: Yes. The State of Washington, I think it’s King County, they have a healthy nail salon program also and they conducted some studies to see if it improved. For toluene, I believe it did. I could get you that information.

DR. KERZIC: Are you doing those results as well?

MS. JACKSON: We haven’t done that. It’s something we could potentially do. We don’t have a lot of funding for the program, but potentially and maybe in collaboration with others who already have personal meters or things like that, we’d be happy to work with you on that.

MR. SCHOON: The Swedish government actually has very good requirements for ventilation in salons, and they have test methods that they specify must be used, so I would recommend looking at what they’re doing. They’ve really made some great headway in salons in Sweden.

MS. JACKSON: I think for us when we started
this program we did a lot of stakeholder meetings
with people in the industry, people who were working
in salons, salon owners, and loud and clear we heard
that, “Please, please, this is our bread and butter.
Don’t put us out of business. Don’t go telling
people not to have their nails done.” And so okay,
yes, we hear you.

And so what we really had to do was figure
out practical solutions that weren’t going to be so
cost prohibitive. And so again, requiring a whole
change out of an HVAC system, working with someone’s
landlord, that kind of thing, it’s really, really
difficult. And the way that’s being handled in other
communities is that it’s only for new construction.

For us in San Francisco, we have a building
stock of 100 or more years, and so it’s really
challenging in a really densely packed city to do
that kind of renovation.

But if there were a new salon -- and
actually, we have a couple new salons who have come
into the program who from the very beginning before
eyen really started construction of their salon,
they worked with us to figure out what kind of system
to put in place, so it can work.

MR. SCHOON: The risk that you run is that
people just won’t start new salons. We’re seeing this in New York now. It costs too much money. The State of New York doesn’t allow for ventilation systems like this, which I think was a big mistake on the State of New York’s part.

MS. RUBIN: Paula?

DR. JOHNSON: I wanted to mention that the other side of the argument that if there’s no data showing harm then why discontinue using certain chemicals.

The other side of that, if there’s no data showing safety, why expose thousands of people to that exposure?

MS. RUBIN: Are there any other comments or questions in the room? Go ahead.

MS. ALCANTAR: Kathryn Alcantar from CEH. I have a question, maybe more directed to DTSC, which is: I really appreciate the opportunity to have various stakeholders come and present and really learn more about the industry and how it operates.

From our perspective, one of the things we appreciate about the program is that it’s very different than other programs because of this focus on hazard. And so, I have to say that a lot of the conversation around personal protective equipment and
reducing risk, of course we want to reduce that risk, but putting that burden on low wage immigrant communities with limited English speaking proficiency is very problematic. I would just want to encourage DTSC to utilize in full effect its authority to focus more on hazard necessarily not having to do risk assessment.

Those lists have been vetted by authoritative bodies, so this concept of well, let’s study it further, the point of the program is to prevent that from happening and really look for alternatives, so I just want to make sure I got that in.

And then the second piece is, I’m not an expert on the nail product manufacturing process, but the presentations and conversations today I think rightly so have focused on the health hazards for workers and consumers directly.

But the other element of the Safer Consumer Products Program is the attempt to look at a product’s hazard throughout its life cycle. I’m curious if the Department has reached out to manufacturers to better understand, for example, what worker exposure might be in the manufacturing of these products.
And then, conversely on the other side, from manufacturer all the way to disposal, how are they being disposed?

One of the people said hand washing is much more common. If you’re hand washing down these products, how much of that is getting into the water stream?

And also, having learned from the pharmaceutical industry in terms of things being washed down the drain, how are people disposing of this? I have to say I’ve accumulated bottles of nail polish throughout my life, and thus far, I’m not quite sure what to do with. Do people just throw it away? What does that mean? How is it getting into our environment? So we haven’t talked about any of those today, and I just want to call that out and see if there could be further discussions to that end.

MS. JACKSON: Could I just add to that?

MS. RUBIN: Of course.

MS. JACKSON: We have seen, especially on the disposal side, a lot of problems: acetone being poured down drains which, of course, is probably not very good for plumbing. All sorts of things being disposed of improperly, and of course in our program we train folks on what they need to do for proper
disposal; take it to household hazardous waste facility, which in our community small businesses can use. That’s not true everywhere. And, of course, all of the salons that are not in our program have not necessarily received that training.

I don’t believe that it’s part of the BBC’s training. It would be great if that were true, but it’s a really big problem.

And to your other point, if we can try to eliminate some of these toxics in the products in the first place then we don’t have to deal with the disposal issues.

I used to work in the wastewater industry for many years and a way is down drains and in the garbage and then you never think about it again until it ends up in your groundwater. It’s a really terrible problem, so nothing really ever goes away.

MS. RUBIN: Thanks Jen. Do we have any more questions or comments from anyone in the room? No one online? I want to thank you all and introduce Dr. Meredith Williams, our Deputy Director of the Safer Products and Workplaces Program.

DR. WILLIAMS: Thank you. Thank you for doing such a great job today and thanks to the entire
team for giving everybody this opportunity to really
share the information with us.

I am very heartened by the discussion today,
just because we invite a discussion and you never
know if anybody’s going to show up and really give
you meaningful information, and I know that we
learned a lot today and we do consider this
fundamental to our decision making process.

This is a new program. It is a new
paradigm. You saw that today. I’m heartened by the
level of understanding of how these regulations work,
but I still think we have more to do to talk about
where we are in that spectrum between hazard and risk
and how we make our decisions. We’ll continue to
provide as much transparency about those things as
the program evolves.

I often say that we’ll be successful not if
we just name a bunch of products, but if companies
start to think the way that we think. So, if
manufacturers start to think about “what’s worth it”
in terms of their product formulations, we think
we’ll be getting somewhere.

I think today we got some indications that
people are wrestling with these issues. They’re
willing to be in conversation with us. We have very
knowledgeable people from the NGO community who are plugged in and we’re very grateful for that, and I think that puts us in a good position to continue to move this topic along, along with our other topics, and get to the point where we can make decisions about what we want to do in this space, if we want to do anything.

Thank you all for your attention. It was a long day but it did seem to me to move along at a great clip in terms of just having the variety of speakers and covering a lot of ground. We hope that you will stay engaged and continue to reach out to us.

There is contact information on the agenda for everything from media inquiries to the technical information.

There’s still time to comment through CalSAFER. Please use CalSAFER, our online tool for comments, and please be in touch.

Thank you.

MS. RUBIN: Thanks, everyone.

(Adjourned at 4:19 pm)
I do hereby certify that the testimony in the foregoing hearing was taken at the time and place therein stated; that the testimony of said witnesses were reported by me, a certified electronic court reporter and a disinterested person, and was under my supervision thereafter transcribed into typewriting.

And I further certify that I am not of counsel or attorney for either or any of the parties to said hearing nor in any way interested in the outcome of the cause named in said caption.

IN WITNESS WHEREOF, I have hereunto set my hand this 20th day of March, 2017.

Susan Palmer
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