FDA U.S. FOOD & DRUG ADMINISTRATION

PUBLIC MEETING

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FDA

Wiley Auditorium

5001 Campus Drive

College Park, Maryland 20740

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A P P E A R A N C E S

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C O N T E N T S

P R O C E E D I N G S

DR. KATZ: Okay. Good afternoon. We'll go ahead and get started. And I thank everybody for coming to our Public Meeting in preparation for the 2017 International Cooperation on Cosmetics Regulations Meeting which will be held in Brazil in July of this year.

I just would like to give you a few brief comments before I go ahead and get started. Basically, if anybody needs to leave the room, please go up to the back and someone will escort you to wherever you may need to go. When we're done with the meeting, again, we'll exit towards the back.

So, let me begin with just a little bit of some history, and then I will go ahead and begin my slide presentation. We also have two presenters that are on our list for today and we have people who have also opted to call in this year on WebEx.

For those who are on WebEx, just as a

reminder, please make sure that your phone is on mute.

The purpose of the Public Meeting is really to go ahead and invite the public input on various topics of interest that may pertain the regulation of cosmetics. This may also help us in further discussions at our ICCR meeting that will be held July 12th through 14th in Brasilia, Brazil.

ICCR is a voluntary international group of cosmetic regulatory authorities that are from Brazil, Canada, the European Union, Japan and the United States. These regulatory authorities meet annually and have dialogues with relevant cosmetic discussions that are also important to our cosmetic industry and trade associations and other political groups.

The purpose basically of these meetings is to help us to develop consensus using the compatible laws, policy, rules, regulations and directives that may pertain to all of our governments. The important thing to keep in mind is that through

all of our discussions, that it's up to each individual jurisdiction to use the information as they so please. ICCR does not make or create regulations, and, in fact, when ICCR's agenda consists of topics of interest to all the regulators that would not require implementation of new regulations in any particular jurisdiction.

So, this afternoon, what I'd like to do is to talk a little bit more about ICCR and its process, talking a little bit about the history of ICCR and how it came to be. I'd like to give a brief summary of what happened in ICCR-10 last year and talk about some of the upcoming issues for this year's meeting.

This slide is actually an old slide, but it's relevant because basically it talks about when the agency first started to deal with international harmonization. This policy was established back on October 11th, 1995. Part of the reason for this was basically to facilitate international trade and promote mutual understanding, facilitate

exchange of scientific and regulatory knowledge by foreign government officials to the extent permissible by law, to accept equivalent standards compliance activities and enforcement programs of other countries, if such programs would meet FDA's level of public health protection and to avoid the lowering of public health protections. In other words, to avoid downward harmonization.

When the international harmonization efforts first started to take place, they took place on the drug and the device side and subsequently moved to cosmetics after several years. In fact, the first predecessor of ICCR was CHIC. Some of you may or may not remember CHIC in the audience. CHIC was the Cosmetic Harmonization and International Cooperation.

The first meeting of CHIC was held in April of 1999 in Brussels and the host at that time was the European Union. The participants were Canada, the EU, Japan, and the United States, and the goal was to introduce international regulatory schemes,

seeks areas of commonality for regulatory alignment and develop memorandum of cooperation.

CHIC met three more times before deciding it was time to disband in 2005. And part of the reason was we felt that the way CHIC was set up and its memorandum of cooperation, wasn't really established to try to deal with issues of relevance to the different jurisdictions. It was more of a way for us to get to know each other as regulators and to talk about things possibly of interest.

So, in 2006 ICCR was established and its first meeting in 2007 in Brussels. Part of the reason for establishing ICCR, as I mentioned, was basically for us to develop a cooperation and a way for us to deal with topics of mutual interest and really deal with the topics, not just superficially talk about how each of us regulates them.

The members initially were Canada, the European Union, Japan, United States, and in July

of 2014, Brazil joined and became the fifth of our Steering Committee members.

We established ICCR with the terms of reference and we used the voluntary consensus model. And by this, I mean is that we all need to reach consensus before we agree to post a document and that a document is considered complete.

We also based the ICCR on ICH, VICH, GHTF precedents. This was basically to give us, again, some established way to move forward. The one difference between us and the others is that we decided that it was important to have input from our industry trade association partners, and to make them a partner at the table even though we, as the regulators, are the Steering Committee members.

This slide is really just posted to let you know where we've been over the last ten years or so. As you can see, the first meeting was in Brussels. Last year the United States hosted the meeting, and this year it will be held in Brazil.

The work process is set up and it flows in the same way every year, we have an annual meeting with interim teleconferences. And depending upon what the issues are determine how many teleconferences we may have during the year, but we try to at least get together with quarterly calls. The venue rotates among the five regions, and as you would notice from the preceding slide, that you can see each of the five regions takes their turn.

For the United States, before each annual meeting, we will announce a Public Meeting in the Federal Register, such as this one. And we usually try to hold that anywhere from four to six weeks before the actual meeting. The hosting country or region chairs the ICCR meeting and it provides for the secretariat for that year.

And the ICCR may constitute a variety of subsidiary working groups, and some of those you'll hear about when I tell about the results from last year.

So, the actual meeting structure has been fairly constant for the last four or five years. On the first day it's a regulators-only meeting, and that's where regulators will meet with each other, talk about issues that are relevant as for regulators.

The second day is a regulator-plus-industry meeting, and the third day is a regulator-only meeting, which, again, is used to talk about which documents need to be adopted and what the outcomes were of that meeting.

Following the meeting, a press statement that was developed will get posted.

The stakeholder open session is held on day two of the meeting, and that's where stakeholders, who desire, may have an opportunity to present.

The outcome of ICCR is posted now on our ICCR website, which has been in existence for about the last four years. On the website are deliverables, the accepted documents and we've actually gone back into time to the first ICCR are posted.

So, this slide shows you the agenda items for the ICCR-10 that was held last year. I'm not going to go through each individual item I'm going to summarize them as I go through what the outcomes were from each and the meeting itself.

With regard to governance, the regulators provided an update on ICCR expansion and criteria and process. The outcome was that the ICCR will remain within the scope of the terms of reference and that the Steering Committee will continue to follow a consensus decision-making process.

The relevance of this is that as ICCR gets larger, it's important to keep in mind that we still believe consensus is the way to go as, opposed to a plurality or majority.

With regard to integrated strategies for safety assessment of cosmetic ingredients, ICCR adopted the document called Integrated Strategies for Safety Assessment of Cosmetic Ingredients and the terms of reference was posted to the website.

With regard to aggregate exposure assessments

for ingredients in personal care products and cosmetics, a formal presentation was made by industry and there was no direct outcome from that.

With regard to international standards, ICCR adopted the International Standards in Cosmetics Report, and that was posted to the website. And this is the standard of microbiological standards. In addition to that, a table of the standards was posted and it was agreed that it would updated every three years.

With regard to cosmetic preservation, a "Frequently Asked Questions" document was posted on the website at the end of November 2016. What the outcome actually was for 2016's meeting was that it was translated into 23 different languages, and that, again, is available on the website.

The agreement was that we would continue to work on a cosmetic product preservation infographic and that the work has expanded to

include other communication specialists to make sure that the infographic really gets across the message to consumers as well as industry.

With regard to microbial contaminants, ICCR adopted the Microbial Limits - International Organization for Standardization, ISO-17516, and that report was also posted to the website.

For allergens, ICCR adopted the white paper "Survey of Approaches Undertaken to Develop Lists of Potential Allergens in Cosmetics - Allergen II: Part 1." Next steps were proposed by the work group as to how to go forward in terms of trying to identify allergens that are found in cosmetic products.

With regard to traces, that there two white papers that were adopted. One was "Considerations on Acceptable Trace Levels of 1,4-Dioxane in Cosmetic Products," and the other was the "Recommendations for Acceptable Trace Mercury Levels in Cosmetic Products."

We heard in addition to all of these updates

from observing regulators, and these included regulators from Columbia, Korea, South Arabia, Saudi Arabia, South American, and Taiwan.

With regard to involvement of interested parties, the regulators finalized the criteria to allow interested parties to submit detailed proposals for work items. And that, again, is posted on our website.

We also put in additional information for new regulators, international trade associations, NGOs and academia on the web. Participation, again, is as observers; and an open session for the stakeholders, as I mentioned, would occur on day two of the meeting.

This year ICCR will be held in Brasilia. We've been holding regular teleconferences and work meetings throughout this year.

The agenda itself will continue with discussions on governance, microbiological standards, integrated safety strategies for safety assessment, cosmetic product preservation, and the

Allergen II work group will present their final report and any new proposed agenda items.

This slide is placed here so everyone can have the access to the International Cooperation on Cosmetics Regulations website. This website is kept up to date and any time that there is a new posting, it will be available there.

The website has several of the older documents that have been posted, in the past, and documents that will also describe a little bit more about how ICCR operates.

And with that, I'd like to thank you for your attention and go on to our next speaker, and that would be Monica Engebretson from Cruelty Free International.

MS. ENGEBRETSON: Okay. So you've probably all been able to read this in the packet by now. Just a little brief introduction.

So we were formally the BUAV and we led a 20-year campaign working towards a ban on the use of animals in cosmetic products in the European

Union. We're now working in many countries around the world to adopt similar regulations. Working with governments and regulators around the world, we have people in Brazil, United States and work with partner organizations in India and Vietnam, Korea, and many of the other major cosmetics markets.

So, given the remit of the ICCR, we particularly would like to look at how a non-animal testing level playing field and harmonized roles could be good for industry and good for trade and what we can all do to assist countries that need support to adopt validated, recognized alternatives.

As people know, the need for animal testing is rare. Existing ingredients are plentiful, which already have safety data which are frequently used just to recominate (ph) to make new products. Non-animal methods, of course, have been developed. In the rare case where a -- maybe an alternative isn't quite developed, those tests are usually not

used for cosmetic purposes. So, all the tests that are usually used to carry out safety assessments for consumers have alternatives that are typically cheaper and often faster and better able to predict human outcomes than the animal tests that they replace.

In the cases of areas where they are still being developed, as I mentioned, and validated, those tests aren't usually used for cosmetics such as the carcinogenicity test, and that's not usually carried out for cosmetic products because of the threshold of toxicological concern, it doesn't usually rise to the level of needing to run that test, and that test takes up to two years to complete and is only about 50 percent predictive of a human response anyway.

Cruelty Free International has a comprehensive and up-to-date information and analysis available about the status of the different alternatives and would like to offer ourselves as a resource for the ICCR.

The use of non-animal tests has been following an upward trajectory for at least the last 20 years, and the most significant boost came with the European Union bans, which came in as a phase and effect with 2013 being the ban on import or marketing of any product that's been tested on animals.

In September 2016, an attempt to weaken that ban was thwarted when the Court of Justice confirmed that cosmetics containing an ingredient that was tested outside of the European Union can't be sold. We were the only NGO that intervened on that case, so if there's questions about the details of that, I can get those for you even though I don't have them right now. That would be something we can do.

But moving on from there, since the European Union ban came into effect, ten other countries have adopted some form of regulation. They're all a little bit a little bit different, but that resulted in over half of the, you know, global

cosmetics now prohibited animal testing. And so, of course, once again we would like to look at a way that a harmonized -- more harmonized schedule, something closer to the European Union ban across all markets could be achieved.

And we can kind of color Australia pink and Guatemala pink since the time that this slide was made.

So, there's three issues these are the three issues that typically come up when talking about harmonizing regulations: REACH, or how does a cosmetic testing ban interact with other testing schemes for chemicals or other products.

Innovation, and China. And I'll just go over these really quickly. So, with REACH, like a question is if an ingredient is tested under another testing regime, can like REACH or any other chemicals, can it be then submitted for cosmetics. And there's really three options that each country needs to decide how to handle it. One would be if it was tested for another regime,

then it can't be used for cosmetics.

The other option would be that the results of the animal test can't be used, even if they've already been run, they can't be used to determine safety for cosmetics. You would still have to submit the non-animal test. Or to say that the results can be used even if they're because they were used in another product.

The EU Commission position is somewhere between the second two. It says that the test is not acceptable if the ingredient was developed primarily for cosmetics purposes. But if it was developed for use in another product where the animal test was used and then later found to be useful in cosmetics, then they will allow that.

Innovation is another common concern. This is just addressed because only in about three to five percent of new cosmetics actually have a new ingredient in them, and many of them have been tested either in other under other testing regimes or they can be proven safe by the non-animal

testing methods that already exist. And, of course, at some point the consumer demand for innovation is balanced by a consumer demand with cruelty-free cosmetics, and with innovation, with the when the cosmetic bans came into place, there was also a huge boost in the innovation of human relevant tests. So, the innovation in alternatives tests and innovation in cosmetics and meeting consumer demand can really go hand in hand.

And since the European Union ban, kind of an example of this, consumer safety has not been jeopardized by the ban and consumers still have a lot of products to choose from.

This third point is China, because it is the only country that has required animal tests for the marketing of cosmetics. But even that is shifting and becoming less of a concern, and we expect to see a continued lessening of requirement from China.

In 2014 there was changes made that would

allow a test to avoid animal testing if the product is manufactured in the country. And in 2017, just this last March I think it was, there was a new simplified registration process for imports that might allow companies to avoid testing when imported through Shanghai.

So once again, we would like to encourage a robust discussion at the ICCR meeting about what is needed to move the global regulations in the direction of non-animal testing and adopt more of a cruelty-free standard across the board and to encourage the use of the alternatives. So, three things that at minimum we think that it might be used to discuss an actual goal line for the ICCR because the current position is obviously very frustrating and confusing for consumers as well as difficult for industry.

Could -- one thing that could be considered is a mandate on the use of alternatives. That would be -- so where an alternative has already been validated by international bodies, doesn't it make

sense that that alternative then is required to be used before resorting to animal tests?

Three states already have this law in the United States, California, New Jersey, and New York. And we think if these modern alternatives are agreed, shouldn't they then be required to be used before resorting to the animal test?

The second point that we hope can be discussed is maybe it's time for a timeline, setting out a reasonable target for the phasing out of animal tests. Setting a target gives time for regulators and industry to adjust and to anticipate what's coming forward.

So that's the end, and thank you for allowing me to take some time, and we're here for any questions you may have. And once again, we hope that the ICCR meeting will address these issues.

Thank you.

DR. KATZ: Our next speak is Megan Polanin from the National Center for Health Resource.

DR. POLANIN: Thank you for the opportunity to

speak today. My name is Dr. Megan Polanin. I am a senior fellow at the National Center for Health Research.

Our research center analyzes scientific and medical data and provides objective health information to patients, providers and policy makers. We do not accept funding from industry so I have no conflicts of interest.

We continue to be concerned about the presence of endocrine-disrupting chemicals in cosmetics and their effect on consumers' health. Some hormone disrupters such as phthalates and parabens are found in a wide range of cosmetic products. Others are used in specific cosmetics such as triclosan in toothpaste and UV filters in sunscreen.

Children and adults are exposed to many different soaps, creams, and other cosmetic products every day and, thus, are exposed to multiple doses of endocrine disruptors.

Low molecular weight phthalates such as DEP,

DBP, DIBP, and DMP are still found in many cosmetics. Prenatal exposure and as a young child are associated with increased behavior problems, decreased cognitive function and more attention problems.

Parabens are used in cosmetics as preservatives. They are associated with oxidative stress, DNA damage of sperm, altered thyroid hormones, and increased risk of allergies. In addition, parabens are associated with breast cancer tumors and their growth. In at least some cases, the health effects are stronger when multiple parabens are present such as from use of several cosmetic products.

Phthalates and parabens are found in virtually all adults. They move into human placenta and milk where they harm fetal and infant development. Cosmetics substantially contribute to overall exposure to endocrine disruptors. A 2016 study of adolescent girls found that just changing the cosmetics that they used reduced the amount of

specific phthalates, parabens, and other endocrine disruptors by 27 to 45 percent. This study needs to be replicated, but it suggests that cosmetics provide a substantial exposure at a vulnerable age.

One of the problems with evaluating the impact of endocrine-disrupting chemicals is that they can have an impact at very low concentrations and show a U-shaped dose response. The National Institute of Environmental Health Sciences has explained that smaller doses can have stronger effects than larger doses. This is particularly problematic in measuring the impact of exposure during critical developmental windows such as during fetal development, as a young child, or during puberty.

We strongly urge the ICCR to have a thorough discussion about the issue of endocrine disruptors in cosmetic products as well as policies to reduce exposure.

Not all phthalates and parabens are endocrine disruptors, and eliminating all phthalates and

parabens from cosmetics would not eliminate all exposure. However, changing known or suspected endocrine-disrupting chemicals to safer alternatives would substantially reduce overall exposure for many adults and children. In products where these chemicals are necessary, they should be clearly labeled so that consumers have the option to avoid them. These actions would reduce the risks of endocrine-disrupting chemicals on consumers' health.

We support the ICCR's attention this year to two such endocrine disruptors, mercury and 1,4-dioxane. The Regulators' Industry Traces Working Group concluded that the maximum allowable mercury levels in cosmetic products should be kept below a target level of less than or equal to one parts per million mercury.

In addition, the Trace Elements Working Group recommended lower levels of 1,4-dioxane in finished cosmetic products to 25 parts per million for phase one and 10 parts per million for phase

two. However, 96 percent of products studied were already at this level and 90 percent had less than 10 parts per million. This recommendation seems to be based on the status quo rather than sound science.

This issue is similar to the FDA's recent recommendation for a maximum level of lead in cosmetic lip products. No research was conducted to determine whether the FDA's proposed recommendation is actually safe for consumers, but instead, the chosen maximum level is consistent with lip products currently on the market.

These recommendations would clearly create a disincentive for the cosmetic industry to reduce levels of these toxic chemicals in their products. Consumers deserve to know about all the chemicals in cosmetic products so that they can make informed health decisions for themselves and their families.

The ICCR and FDA have a responsibility to set high standards for manufacturers so consumers are

no inadvertently exposed to products that harm them, particularly given that manufacturers do not have to disclose these toxic chemicals on cosmetic labels. They have failed to do so. This is especially discouraging since the ICCR and FDA are merely making recommendations with no enforcement mechanisms.

In summary, endocrine-disrupting chemicals and other harmful substances are present in many cosmetics in the United States. These substances can harm the health of adults and children and it is essential for the FDA and the ICCR to consider the growing evidence for their harm. We urge the FDA and ICCR to establish high standards for maximum levels of endocrine disruptors and require manufacturers to clearly label their presence in products.

Thank you for your time and consideration of our views.

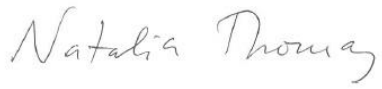
DR. KATZ: I would like to thank everyone for their time and attention. We have reached the end

of our meeting and of the requested speakers. So with that, I will say that we're adjourned. And thank you again for coming.

CERTIFICATE OF NOTARY PUBLIC

I, NATALIA THOMAS, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter

reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



NATALIA THOMAS
Notary Public in and for the
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I, PAMELA J. ALEXANDER, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

6/6/2017 Pamela J alexander

DATE PAMELA J. ALEXANDER