PREPARATION FOR THE 2019
INTERNATIONAL COOPERATION ON COSMETICS
REGULATION (ICCR)

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A P P E A R A N C E S

ON BEHALF OF FDA, Center for Cosmetics and Colors

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P R O C E E D I N G S

DR. KATZ: Good afternoon. I'm Linda Katz. I'm the Director for the Office of Cosmetics and Colors here at the FDA. Everyone who's here, hopefully is here for the public meeting that we're having in preparation of the 2019 International Cooperation on Cosmetics Regulation, ICCR-13 meeting, which will happen in July in Montreal.

Before we get started, I just wanted to go ahead and clear up some housekeeping items. If everyone can turn off cell phones, other personal electronics they have so as not to disturb the people who will be speaking, I would appreciate it.

If for whatever reason you need to leave the room to either use the facilities or to leave in general, please go up towards the back of the room and someone will escort you towards the front door, or wherever else you may need to go.

So, with that I'd like to go ahead and get started. Okay, let me begin -- and what I'm going to do in the next, probably 10 minutes or so, is talk about ICCR or the International

Cooperation on Cosmetic Regulation.

What I will do, in the time that I have, is talk about ICCR and its process. I'll go through the summary of ICCR-12 and the outcomes. I will describe a little bit about the upcoming issues for the ICCR-13 meeting that will be coming up as I said next month in Montreal, and give some instructions at the end for submitting items to ICCR for proposals for the future discussions.

So, let me begin. ICCR started as an offshoot of FDA's policy on international harmonization, which was -- began, back in October of 1995. At that time, the FDA began to talk about how to have international harmonization amongst the varying products that it regulated, not just cosmetics, but also for foods, devices, drugs, et cetera.

And basically, the overarching goals were to include: facilitate international trade and promote mutual understanding, facilitation of the exchange of scientific and regulatory knowledge with

foreign government officials, and to promote transparency, to the extent permissible by law. Accept equivalent standards, such as compliance activities and enforcement programs of other countries if such programs met FDA's level of public health protection. And finally, which is key, to avoid lowering of public health protection afforded by U.S. law --that is, to avoid downward harmonization.

So, the first of the cosmetic international organizations that was established, was the Cosmetic Harmonization and International Cooperation, commonly known as CHIC, back in April of 1999.

The first meeting was held in Brussels, and the participants at that time were Canada, the European Union, Japan and the United States, specifically the FDA.

The goals were to introduce the different partners of international regulatory schemes, to seek areas of commonality for regulatory alignment and to develop a memorandum of cooperation.

CHIC met three times, the last was in Canada

in 2005. Back in 2005, when we met for the last time as CHIC, the group decided that CHIC was nice, we got to know each other and we got to form regulatory relationships, but that we really never solved anything, and the meetings became more of a process to inform each other. We weren't really established in such a way as to get any agenda items accomplished or to work on any specific items.

So, in 2005 we decided we would disband CHIC and form ICCR. And we actually established ICCR in 2006 and held its first meeting in 2007. The members at that time were the four members of CHIC which included Canada, the European Union, Japan and the United States.

In 2014, Brazil became the fifth member of the Steering Committee. We formed a term of reference, and we decided that we would set up our standards using a voluntary consensus model. And we would model ourselves off of other international harmonization groups at the time, which included ICH, VICH, GHDF.

And that basically, the one exception, that we

had from the other groups, was that we were going to get integral input from our industry trade partners -- our industry trade associations. The goal was still to remove any regulatory obstacles among regions and to minimize the obstacles to international trade while retaining the highest level of consumer protection.

And again, we were to avoid downward harmonization. We also agreed as part of our voluntary consensus, that we would not deal with any issues that required changes in one area's regulatory schemes.

So, that the areas that we chose to work on would be areas that we could choose to have alignment or cooperation, rather than having to adopt someone's current regulations.

The ICCR work process is: the meetings rotate amongst the five regions, and in another slide, I'll show you where we've been over the last 13 years. We would hold an annual meeting and have interim telephone conferences, usually quarterly, hosted by the country or region chairing the ICCR meeting. They would provide for the

Secretariat function for that year.

ICCR also may charter subsidiary working groups, and that the U.S. had agreed when we formed ICCR, that we would hold a public meeting such as this one, prior to the actual ICCR meeting to allow for stakeholders to participate and to give us information that they would like for us to share with the rest of the ICCR members.

The public meeting, as you saw, was published in the Federal Register. The structure of the annual meeting is as follows. The first day is a regulators-only meeting. The second day is regulators plus industry. The third day is a regulators' meeting only. At that time we would adopt the outcomes of the meeting at the close, prepare press releases or any other additional information that we would like to make sure got posted publicly.

In addition, we began a stakeholder open session that would be held on day two, for stakeholder participation. Usually this includes only stakeholders from the jurisdictions chairing the meeting.

The outcomes of the ICCR meeting now are posted on ICCR's website. I've left you the website information here, which shows the deliverables, the accepted documents and any other useful information that we've had over the course of a year.

Prior to the time of having the ICCR website, we would make all of the information that was pertinent available publicly, in the form of a press release.

So, these are locations of where we've been. As you can see, ICCR-1 started in Brussels and last year we were in Tokyo, and this year we will be in Montreal, Canada.

Just to highlight, the last one that U.S. hosted, was ICCR-10, and we will be hosting ICCR-15, as a coming attraction. These are all of the individuals who participated in ICCR-12 in Tokyo, and this includes not only the regulators, but also our industry partners.

The ICCR-12 agenda basically had the

following items: Integrated strategies for safety assessment of cosmetic ingredients; Analytical test methods; Cosmetic product preservation; Allergens; Communications; the Microbiome; Updates from observing regulators; Industry update on e-commerce, and stakeholder presentations.

I'll go through in a little bit more detail just to summarize what occurred. So,with regard to the Integrated Strategies for Safety Cosmetic Ingredients, the ICCR's Steering Committee adopted the Integrated Strategies for Safety Assessment of Cosmetic Ingredients - Part II.

This is a white paper or report which describes strengths and limitations of new methodologies and it was posted to the ICCR website. In addition, ICCR Steering Committee agreed that the current work of the Joint Working Group would continue on, and it would form the case study -- that would be discussed at the next ICCR meeting as Part III.

As part of the preparation for the items in Part III, a meeting is being held in Canada on the 11th

and part of the 12th to go over some of the information and to work on the case studies to help formulate the next white paper.

The Analytical Test Methods was also discussed. The Steering Committee accepted the Review of International Standards on Analytical Methods defined by ISO.

The report itself was endorsed and three ISO standards were endorsed and posted on our website after agreeing with the validation criteria.

ICCR also agreed to open the Joint Working Group to update a table of relevant ISO standards that could be used in the future.

The next report was Cosmetic Product Preservation. The Steering Committee agreed that the current Joint Working Group would continue to work on a white paper that will establish and evaluate the relative cosmetic preservation, preservative pallet. This arose from information that we had on cosmetic preservation, and the need to try to figure out which preservatives still could be used and would be

safe to be used in cosmetics and to what degree.

The Allergens work group -- the Steering Committee agreed that the Joint Working Group's assessment of non-animal methods in the evaluation ofskin sensitization potential -- that report is going to be continued to be worked on and eventually will be posted on the website.

For Communications, the ICCR agreed to create a new Joint Working Group on communications that would include topics related to cosmetics for a broad audience. What this basically means is that we're trying to think of a way that all of us can communicate some of the same messaging to all of our constituents, so that if there is a message that we want to get out, everyone will see the same thing worldwide.

The Microbiome is a new Joint Work Group, andthis was established during the cycle. It will be presenting the outcomes at the meeting coming in July.

From the observing countries or regulators,we heard from Israel, South Africa, South Korea,Taiwan, and Thailand. Israel discussed their license

and registration program. South Africa discussed harmonization with some of the European Commission regulations.

South Korea talked about their notable growth in export market. Taiwan discussed their new cosmetic act, animal testing ban and upcoming notification requirements. And Thailand talked about their harmonization and free trade issues with the Association of Southeast Asian Nations known as ASEAN.

Industry presented an update on e-commerce which is a way to facilitate cooperation and increase global consumer protection. These presentations were intended to stimulate discussion which they did, but there was also some concern that some of the areas in the discussion went beyond the jurisdiction of those at the table. The suggestion was to table it right now and perhaps at some point in time we would evaluate it again.

With regard to stakeholder presentations -- the bulk of the presentations made by stakeholders were on animal testing, and what other alternatives could be done to avoid testing or minimizing animal

testing itself.

And it's important to note that ICCR has recognized the importance of alternatives to animal testing, and it continues to work on this topic. In the past, we've posted information as to what alternative tests can be done that have been validated.

Some of the specific tests are that are being looked at now are being done in a variety of different subgroups as opposed to one specific alternative subgroup which previously had met in the past.

With regard to last year, we had an International Symposium on Cosmetic Regulation that followed the ICCR-12 meeting. Japan decided to host such a meeting in which representatives from the ICCR jurisdictions participated. The event was open to Japanese cosmetic industry, academics and others who felt that they would like to come and hear what the regulators had to say.

So, that brings us up to ICCR-13. As I mentioned, Canada is hosting this year in Montreal and

it will be from July 9 to 11. During this past cycle, we've had quarterly interim teleconferences, and the work groups have continued to meet to create the documents and the information that will be presented at the upcoming meeting.

The agenda is as follows. We will continue to talk about the integrated strategies for safety assessment of cosmetic ingredients. We will continue to talk about cosmetic product preservation, allergens, international standards, communication, microbiome and any other new proposed agenda items that are proposed before the meeting time.

Finally, what I'd like to do before I get to the website one more time, is to show a slide with instructions for submitting future ICCR action items. Years ago, as there are some people in the audience who may remember, on our previous website we did have instructions for how to submit an action item, or agenda item for those who had something for us to consider.

For whatever reason, when the ICCR website was migrated, it seemed to have disappeared. But the

bottom line is that the FDA does invite public input on future ICCR agenda items. If there are specific items that you wish to have considered as part of an agenda item, please let us know. That should be done in writing to Jonathan Hicks and I have his email here.

If after this meeting, you think about it and have a formal item that you would also like to have discussed either at the next ICCR meeting, ICCR-13, or ICCR-14, please make those written requests as well to Jonathan Hicks and we will make sure that the Chair or the Secretary of the next ICCR meeting is informed.

The one thing that I will suggest is that if you're going to make a request, the request needs to be specific enough so we know what the questions are that someone would like to have ICCR address, and if there's any supporting information that you have that the ICCR needs to review to be able to talk about the topic, please submit that as well.

And one last thing is again remember that we

cannot recommend changes to member laws or regulations. This slide shows our ICCR website and actually it's organized so that you could find out about all of us. It talks about the composition of ICCR, the Chairmanship and who's led which meeting.

All of the topics and any documents that we've agreed to have been posted on that website. I thank you for your attention and let me now turn over to our next speaker who would be Jay Ansell, from Personal Care Products Council.

DR. ANSELL: Thank you Linda. So, good afternoon. My name is Jay Ansell, and I'm the Vice President for Cosmetic Programs at the Personal Care Products Council. I'd like to thank FDA for holding this meeting and for its interest in soliciting the viewpoint on ICCR processes from the stakeholders.

On behalf of our industry, I am pleased to once again take this opportunity to emphasize our industry's strong support for the ICCR process. We would also like to express appreciation to FDA and to the other participating regulators from Europe, Japan, Brazil and Canada for their participation and support

of the ICCR process.

We believe ICCR has been and will continue to be a beneficial forum for the exchange of information and regulatory alignment between important markets for cosmetic and personal care products.

As a brief introduction, the Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, our more than 600-member companies manufacture, distribute and supply the vast majority of finished personal care products marketed in the U.S.

For more than 100 years, regulators, policymakers, have relied on our organization to deliver honest, credible, accurate, scientific information about cosmetics and personal care products. We take this responsibility very seriously.

And we were pleased to represent our industry in the ICCR process. Now, the cosmetic and personal care industry is truly a global industry, and as such we are dependent on open markets and transparent, consistent regulatory environments around the world.

Our member companies continually strive to uphold and to surpass the most stringent regulatory standards worldwide, providing consumers with the safe, innovative and high-quality cosmetic and personal care products they've come to expect.

International harmonization is a critical component to the success of our industry. It promotes continual technologic innovation and benefits consumers around the world.

For all these reasons, PCPC is actively engaged in the international effort to align global safety and regulatory standards for consumers to eliminate trade barriers, and to ensure a level playing field for member companies while at the same time reinforcing consumer confidence in product safety.

The stated mission of ICCR is to maintain the highest level of global consumer protection while minimizing barriers to international trade underscores the important role of FDA and other regulators in this global environment.

We believe that the ICCR has served as an

important forum for aligning regulations, policies and guidelines affecting our industry. And importantly, as a resource for other countries looking to align their regulatory approaches around such common guidelines.

We are looking forward to the results of theICCR-13 meeting. As mentioned -- we look towards an endorsement of a report regarding cosmetic preservation, continued advancement of alternative safety assessment tools for identifying potential dermal allergens, and continuing the dialogue in the exciting new work item on the microbiome.

Let me add ICCR-13 will also have an important workshop on integrated strategies for safety assessment of cosmetic ingredients. The important work undertaken by ICCR has been recognized by industry and regulators in other countries who have reviewed the documents and now, themselves, express interest in participating in the ICCR meetings.

And we’re particularly pleased to welcome to the ICCR-13, representatives from Argentina, Chili,Columbia, Israel, South Korea, South Africa, Taiwan

and Thailand as observers to the meeting.

Our industry fully supports the participation of these other countries in the ICCR process and we are interested to explore other avenues to promote the ICCR work globally, as well as considering synergies between ICCR and other international organizations, for example, ISO.

As international trade and cosmetic and personal care products continues to expand, achieving the goal of global harmony, as regulatory alignment becomes more critical.

And we look forward to working with FDA and the other regulators to enhance the ICCR process in the months and years ahead, thank you.

DR. KATZ: Thank you Jay. Next, we will hear from Deborah Campbell.

MS. CAMPBELL: Hello everyone. I'm Deborah Campbell, President of the American Cosmetic Manufacturers Association located in Washington, D.C. ACMA is a non-profit organization that supports U.S. cosmetic manufacturers and assists them to expand their businesses in the global market.

Since ACMA was founded in 2010, our members have relied upon our organization to deliver the latest standards and regulations set by the FDA for the manufacture and labeling of cosmetic products and encouraging them to uphold consumer protection by producing the highest quality products.

On the behalf of all ACMA members, I would like to thank the FDA and the Office of Cosmetics and Colors for their efforts in planning this meeting. ACMA appreciates the consideration that the FDA has shown by holding these annual meetings that give cosmetic industries and interested private parties, a venue to voice their cosmetic-related concerns before the ICCR Conferences are held.

ACMA would also like to express appreciation for the efforts of ICCR members in supporting the international cosmetic industry while ensuring customer safety.

The participation of new representatives from Thailand, South Korea, Israel, Taiwan and South Africa, and I believe Columbia, as observed in ICCR-12, highlights the interest of ICCR to reach out to

different regions in an attempt to achieve global harmonization of cosmetic regulations.

ACMA strongly supports the outcomes of ICCR-12, held in Tokyo, concerning the integrated strategies for safety assessments of cosmetic ingredients, analytical test methods and allergens.

ACMA is pleased to participate in this preparation meeting for ICCR-13, to speak on the behalf of our members and act as their voice to address their interests.

In preparation for this meeting, ACMA conducted a survey of our members to detect some issues that they have encountered while marketing their products.

The results of the survey shed light on some issues facing the majority of our members. Members exporting to Europe reported difficulties meeting EU directives regarding cosmetic testing, labeling and the different cosmetic export requirements of certain countries within the EU itself.

ACMA believes that a regulatory framework in the safety and distribution of cosmetic products are

the most important factors for the growth of the cosmetic industry. The safety of cosmetic products are regulated by diverse regulatory bodies around the globe which all have their own rules and regulations.

Both the European Union and the United States regulate the manufacture and distribution of cosmetic products in a way that provides consumers with the high-quality products in a high degree of safety. However, because both markets have slight variations, some U.S. companies find it time consuming and costly to comply with EU regulations, especially small and new cosmetic manufacturers.

The FDA regulates cosmetics under the authority of the Federal Food Drugs and Cosmetic Act and the Fair Packaging and Labeling Act. However, the FDA's approval is not required for the distribution of cosmetic products, ingredients and color additives in the market.

It is the manufacturer's responsibility to ensure the safety of its cosmetic products. Manufacturers follow guidelines and regulatory elements set by the FDA and international regulatory

bodies to ensure high-quality products, consumer safety, and the ability to market their products internationally.

However, many believe that the EU, European Union, is stricter in the regulation of cosmetic manufacturing citing EU Cosmetic Directive Annex 2 that reveals a list of 1,300 banned ingredients in the manufacture of cosmetics and comparing it to the list of U.S.-banned ingredients that includes only 11 materials.

But, after examination of both lists, you'll find that the European Union has listed a vast number of ingredients which have never been used in cosmetic manufacturing, such as aircraft fuel, various petroleum refinery biproducts, and carbon monoxide.

Another difference between the United States and the European Union is how both regions define cosmetics. For example, some of ACMA's members that export sunscreen products to Europe, experience various regulatory hurdles as the FDA classifies sunscreens as drugs, while the EU allows the marketing of certain cosmetic products that contain some

medicinal effects.

You can imagine the amount of paperwork needed for a U.S. cosmetic exporter to market a product, classify those drugs in the United States and then market it in the European Union as a cosmetic product.

This same issue is applicable for other products such as anticaries toothpaste and lip balms. For this reason, ACMA supports ICCR efforts to achieve harmonization in the global regulation of cosmetic manufacturing and labeling.

ACMA respectfully requests that the FDA speak on our behalf of their concerns at ICCR-13. In summary, ACMA recognizes and appreciates the efforts of all attendees, FDA and Office of Cosmetic and Color staff, and ICCR members in the development and promotion of the international cosmetic industry.

ACMA plans to attend ICCR-14, to be on the front line of international trade regulation. Thank you for listening.

DR. KATZ: Thank you, and now we'll hear from our final speaker, Mary Hilley.

MS. HILLEY: Good afternoon. My name is Mary Hilley. Thank you for the opportunity to submit these comments on behalf of the Humane Society of the United States, the Humane Society Legislative Fund and our members and supporters.

More than 30 countries, including the member states of the European Union, India, Israel, Norway and Switzerland, with more than 1.8 billion residents, have passed laws banning the use of animal testing for cosmetics, as well as the sale or import of animal-tested cosmetics.

New Zealand, Guatemala, Australia and 7 states in Brazil have also prohibited cosmetics animal testing. Rio is the first state in Brazil to also prohibit the sale of animal-tested cosmetics.

Turkey, South Korea and Taiwan have passed laws limiting cosmetic animal testing. In 2018, California became the first state in the country to prohibit the sale of animal-tested cosmetics.

We urge the FDA to push for global harmonization of laws to prohibit animal testing for cosmetics. HSUS and HSLF and very encouraged that the

U.S., Brazilian, Canadian, European and Japanese regulators continue to work together to discuss harmonization of cosmetic regulations and bring about the uniformity necessary to simplify regulatory burdens on companies selling internationally.

We encourage ICCR to solicit participation of additional countries, either as observers or Steering Committee members to ensure greater harmonization. We were happy to see that the recent report released by the industry and regulator's joint working group, Integrated Strategies for Safety Assessments of Cosmetic Ingredients - Part II, following the recent publication of principles in Part I.

This thorough review of the numerous new approached methodologies available is very instructive and should be helpful to industry in applying non-animal testing strategies to cosmetic safety assessment.

We were encouraged to see that further work is planned by this working group to develop case studies. These will only further clarify how a company can assure the safety of their ingredients

without the need for new animal test data.

We ask FDA to advocate for the continued development and regulatory acceptance of NAMS to assess cosmetics and their component ingredients. We would like to call your attention to a new project Human Society International is leading, with support from the Humane Society of the United States and the Humane Society Legislative Funds.

The non-animal cosmetic safety assessment globally by 2023, is a collaboration with leading stakeholders in the cosmetic's industry, including Avon Products, Estée Lauder, Firmenich, H&M, Loss Unlimited, Lush, Proctor and Gamble and Unilever.

This collaboration's aim is to achieve globally harmonized legislative measures to end cosmetic animal testing and trade, share information on decision-making approaches without new animal testing to develop real world case studies, and invest in education and training programs that will support complete safety assessment of cosmetics without new animal testing globally.

As part of this project, we are hoping to

work with FDA on identifying safety information needs, and in developing training materials. We would also welcome any other opportunities to work with FDA to bring about the acceptance and implementation of NAMS and educate regulators and the regulated-community alike on how to make risk-based cosmetic safety decisions without the need for new animal tests.

On behalf of the Humane Society family of organizations, thank you so much for your time.

DR. KATZ: Thank you, and that brings us to the end of our meeting as no others have requested previously to speak. Before I end, I'd like to take this opportunity to thank several people, only one of whom I see in the room, but I'd like to thank Jonathan Hicks for all his work on this as well as John Gasper from my staff and Juanita Yates who you met out at the registration desk.

So, thank you very much and thank you for attending.

(Whereupon, at 2:39 the meeting was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, NATALIA THOMAS, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of 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

STATE OF MARYLAND

CERTIFICATE OF TRANSCRIBER

I, HELEN VENTURINI, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings 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.

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