U.S. FOOD AND DRUG ADMINISTRATION

Public Meeting

Preparation for the 2016 International Cooperation on Cosmetics Regulation (ICCR) Meeting

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P R O C E E D I N G S

DR. KATZ: Good afternoon and welcome to the Preparation for the ICCR-10 Meeting. ICCR is the International Cooperation on Cosmetics Regulation.

We hold a meeting every year which gets announced in the Federal Register in preparation for the ICCR meeting, which is what this meeting is intended to be.

Before I get started with my presentation I want to just go over some minor housekeeping. Some of it you will find in your Agenda for today's public meeting but just a reminder if anyone needs to use the restroom or needs to leave the room for any particular reason someone needs to escort you if you are not an FDA employee. So someone will meet you at the back of the room to help you.

The meeting itself is scheduled for two hours but I'm gathering that given the amount of requested comments that we have received, it will probably be less than that; so when the last of the public comments is given the meeting will end.

So with that I'd like to go ahead and get

started. And so that again I'm Linda Katz and I am the Director for the Office of Cosmetics and Colors. I am the Lead for the United States FDA to the ICCR meeting itself.

This year what I will do is discuss ICCR and its processes; talk about the results of the ICCR-9 meeting which was held last November in Brussels; and talk about some upcoming issues for ICCR-10.

So let me go back and for those of you who have been here before you'll probably recognize this slide because it is a historical slide, and it is shown to just give a little bit of perspective as to how we got to ICCR and some of our international harmonization or cooperation initiatives.

Back in October of 1995 the FDA posted a policy on International Harmonization and at that time the overreaching goals were to include the ability to facilitate international trade and promote mutual understanding, to facilitate an exchange of scientific and regulatory knowledge with foreign government officials to the extent permitted by law that is to

enhance transparency, to accept equivalent standards for compliance activities as well as other standards including enforcement programs if they met the FDA's level of public health protection, and finally the last thing which is critical is to avoid lowering of public health protections afforded by U.S. law, in other words to avoid downward regulation.

So ICCR was established in 2006 holding its first meeting in 2007. And for those of you who have been coming you will probably remember that ICCR started really as an offshoot of CHIC which was the Cosmetic Harmonization and International Cooperation. And basically the reason why ICCR was founded was because it was felt that CHIC was a way to merely exchange information but, it was not really designed as a forum to establish work groups or work on documents that would be of mutual interest.

So that in 2006 ICCR was established and the four countries that established it were Canada, European Union, Japan, and the United States, all of whom were members of CHIC at that time. As of July 2014 Brazil became the fifth member of our steering

committee.

The terms of reference were originally established back at the time of our first meeting in 2007; and in that meeting the terms of reference referred to a voluntary consensus model. And the modeling itself of ICCR was set based upon ICH, VICH, GHTF Precedents. And we also agreed though to have input from our industry trade association partners so that each of the steering committee members would also have representation by trade partners.

This slide basically points to the ICCR locations starting with the first one which was in Brussels and this year it is being held in Bethesda, Maryland and so the United States is the host. As you will see we are now into our third cycle. All of the member countries have had at least two meetings with the exception of Brazil because again they didn't become a full member until July of 2014.

So how does ICCR actually operate, what is the work process itself? We hold an annual meeting with interim teleconferences. And the interim teleconferences are usually quarterly plus

there are additional teleconferences for Working Group meetings as needed.

As I mentioned, the meeting venue rotates among the five ICCR regions. For the United States, we put a notice of the public meeting and any draft guidelines in the Federal Register. The hosting region is the chair for the ICCR meeting and provides the secretariat function.

ICCR also may charter subsidiary Working Groups and again these Working Groups usually meet by teleconference during the course of the year.

So the specific meeting structure is seen on this slide. On the first day it is a regulators only meeting. The second day it is regulators plus industry and there is also an open session which is for stakeholder presentations. By day three it is again a regulators only meeting and that is where there is adoption of the outcomes of the meeting and we put together what would be considered a press release.

The outcomes of the ICCR meeting are actually now posted on the ICCR website which is

listed on this slide. And so that if you actually go to the ICCR website you will see posting of all the documents and all of the items that we've worked on since 2007.

What I'm going to do now is go through briefly and describe what happened in Brussels in ICCR-9. This slide posts the agenda and basically talks about the items that we did discuss which were governance, allergens, alternatives to animal testing, trace impurities, and in silico and QSAR models, cosmetic product preservation, and new items.

So let me begin with governance because that is usually where we start when we get these meetings going. Through the ICCR governance the regulators provided an update on the ICCR expansion criteria and process; that it was decided that the ICCR terms of reference would remain as it was previously established so that there would be no new modifications because the terms of reference still met the needs of ICCR.

The steering committee also decided that they would continue to follow with consensus decision

making process. This was a discussion point because as the ICCR group gets larger consensus is often difficult to achieve. But it was decided that for five ICCR Members, we could still reach consensus in making decisions.

The alternative test methods was just an update of what ICATM which is the International Cooperation on Alternative Test Methods activities during the preceding year. Previously we had agreed that ICATM would update us twice a year but since the updates really are fairly slow, once a year seemed to be sufficient. When we receive those updates regarding the activities of ICATM, they are addressed. ICATM is made up of the relevant alternative testing groups that come from the countries that are listed but it also includes members from Korea.

The industry proposed a new joint Working Group to look at integrated methods for safety assessment of ingredients in cosmetic products and this will be discussed in ICCR-10.

With regard to international standards the

industries presented a report on the international standards on cosmetics and both industry and regulators agreed to a new joint working group that would look at the current ISO standards that are relevant for cosmetics in order to decide which ones may also be relevant to ICCR. The working group would consider and potentially recommend that ICCR adopt such new relevant standards.

In addition we dealt with traces and are still working on the final reports for Mercury and 1,4-dioxane and the chairperson for the steering committee explained a new work process to facilitate future work.

For allergens it was decided again that the joint Working Group would provide an update which it did and worked on some new terms of reference for the Allergen II Working Group. Results from that will be discussed this year.

With regard to product preservation, it was decided to present the information from the product preservation in a document called “frequently asked questions” so that it would be easier for

industry as well as consumers and other constituents to see what was relevant and which questions and answers are helpful with regard to preservation and different regions consider preservation.

Following the acceptance of that document which is posted on the website it was agreed upon that there would be a communication and outreach plan and that is to be discussed this coming ICCR meeting.

There was an update from observing regulators and the update was given from individuals from People's Republic of China, Saudi Arabia, South Africa and Thailand. There was also some involvement of interested parties in ICCR and basically we went through and talked about some of the finalized criteria for consideration of new members both in terms of new regulator members, new international trade associations, and NGOs.

There was participation by the observers in the open session regarding areas of interest which included alternatives to animal testing, benefits from regulatory alignment, and counterfeit products, as well as impact on the aesthetics industry.

The ICCR steering committee also reviewed some proposals that were made and other work that was submitted.

That brings us up to this year, which is ICCR-10, and as I mentioned earlier, the United States is the host. The meeting will be held July 12 through 14. And basically through this entire work period which was about eight months, we formed various work groups and had quarterly interim teleconferences and work group meetings.

The draft agenda is as follows. We will come back again and deal with the topic of governance, we will deal with safety assessment or methods from the Work Group particularly regarding in Silico/QSAR models and alternatives to animal testing, microbial contaminants, international standards, cosmetic product preservation, allergens II and the Working Group report, trace impurities, and any new agenda items that may come as a result of this discussion.

So I thank you for your attention.

And I'd like to invite our first speaker to come and speak. And that would be

Tracy Rupp from the National Center for Health Research.

MS. RUPP: Good afternoon. Thank you for the opportunity to speak today. My name is Tracy Rupp. I am the Director of Public Health Policy Initiatives at the National Center for Health Research. I am reading the comment today on behalf of my colleague; her name is Stephanie Fox-Rawlings.

Our research center analyzes scientific and medical data to provide objective health information to patients, providers, and policymakers. And I have no conflicts of interest.

We are concerned about the presence of endocrine disrupting chemicals in cosmetics and their effect on consumers' health. This issue is not new for the ICCR. It was discussed in 2012 and 2013. It appears that the ICCR asked the cosmetics industry for additional information but it is unclear whether that information was provided and discussed since 2013.

Meanwhile research on the health impact of endocrine disruptors has continued and the risk of these chemicals in cosmetics have become more widely

acknowledged. Several different phthalates and parabens that disrupt hormones are found in a wide range of cosmetic products. Other endocrine disruptors are used in specific types of cosmetics such as Triclosan in toothpaste and antibacterial soap and UV filters in sunscreen. Low molecular weight phthalates such as DEP and DBP are still found in many cosmetics. Early exposure to these Phthalates prenatally and as a young child have been associated in later years with increased behavior problems, decreased cognitive function, and more attention problems.

Parabens are used in cosmetics as preservatives. Parabens have been associated with health risks such as the generation of excessive free radicals from oxidative stress, DNA damage of sperm, altered thyroid hormones and increased risk of allergies in humans. 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 as might be the case with the use of various cosmetic products.

Phthalates and parabens are found in virtually all adults. They are transferred into human placenta, newborns in milk where they can harm fetal and infant development.

There is also evidence that cosmetics substantially contribute to overall exposure to endocrine disruptors. The 2016 study of adolescent girls found that just changing the cosmetics they used to reduce the amount of specific phthalates, parabens and other endocrine disruptors by 27 to 45 percent. This study needs to be replicated and extended but the results suggest that cosmetics provide a measureable portion of human exposure to certain endocrine disruptors.

One of the problems of 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. In some cases 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 issues 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. Children and adults are exposed to many different soaps, creams and other cosmetic products every day and thus are exposed to multiple doses of different endocrine disruptors. However, changing known or suspected endocrine disrupting chemical to safer alternatives would reduce consumers' overall exposure. In cases where cosmetics are the major source of exposure to the parabens, Triclosan and some phthalates it can greatly reduce exposure.

In products where these chemical are necessary they should be clearly labeled so that consumers have the option to avoid them. These actions would reduce the risk of endocrine disrupting chemical on consumers' health.

The issues regarding the risk of endocrine

disruptors are similar to the issues regarding lead in cosmetics in that exposure from individual cosmetics are lower than from other sources. However, the ICCR still specified a maximum limit for lead in cosmetics so that cosmetics do not unduly increase consumers' daily exposure.

In summary endocrine disrupting chemicals are present in cosmetics in the United States and multiple types of endocrine disrupting chemicals are detected in almost all people due to their use of soaps, creams, and other cosmetics. These chemicals can harm the health of the people who use them. It is, therefore, essential for the FDA and ICCR to consider the growing evidence for harm caused by endocrine disrupting chemicals in cosmetics.

Thank you for your time and consideration of our views.

DR. KATZ: Thank you. And we will go on to our next speaker who is Carl Geffken.

MR. GEFFKEN: Thank you. My name is Carl Geffken and I represent ICMAD. The Independent Cosmetic Manufacturers and Distributors organization

is a non-profit cosmetic industry trade association representing over 700 mostly small to medium size companies that manufacture and/or distribute cosmetic products, components, materials and services in the U.S. and worldwide markets.

Located in Deer Park, Illinois, ICMAD was founded in 1974 in Washington, D.C. to represent entrepreneurial cosmetic businesses and while retaining that distinction it has become a focused resource with programs that actively support both new, startup, and well-established companies.

A majority of our member companies are small but highly competitive businesses that compete globally for a share in their very creative cosmetic and skin care markets. Furthermore this segment of our industry represents an entrepreneurial growth engine which is vital to cosmetic industry innovation. About five percent of our members are located internationally and represent over 18 different countries although Canada is the most prevalent.

Our members are strongly committed to consumer safety and in fact all have signed an ICMAD

code of ethics when they joined. Participating companies are increasingly global in their market strategies. Because of the smaller size and competitive challenges they have become uniquely aware of the U.S. regulations and the differences in regulatory jurisdictions worldwide. ICMAD has an active EU assistance program to specifically help comply with unique requirements of the European cosmetic regulation and its associated markets.

The association sponsors an annual FDA workshop, a yearly cosmetic technical regulatory forum, and numerous webinars among its other opportunities to provide ongoing regulatory assistance and to address the many technical and safety obligations for our segment of the industry.

In addition the association sponsors numerous legislative activities and takes all compliance responsibilities with utmost concern.

Nine years ago the FDA invited the ICMAD to participate in the ICCR process to represent small business interests within the cosmetics industry sector. We continue to support all objectives and

outcomes that foster a reduction in trade barriers and a leveling of the playing field to allow both business growth and improve service to consumers. As new and more challenging questions and concerns arise demands for consumer safety substantiation increase in relevance as does the need for reconciliation of regulatory interpretations between the different international jurisdictions.

From a historical prospective in 2008 ICMAD sponsored a comprehensive consumer survey of over 2300 individuals to better understand cosmetic ingredient labeling interpretations and we provided data to support broad 80+ percent U.S. recognition of "aqua" as a potential equivalent to the INCI term "water". Our industry continues to experience the technical and economic burden of unique labeling differences when attempting to harmonize products for international sales especially in the Canadian market. While the outcome of the issue had not yet been favorable for us we continue to support any and all measures to align ingredient designations and other labeling differences among major regulatory jurisdictions. With this in

mind ICMAD has been particularly interested in those topics which foster progress for improved approaches to product safety evaluation a unified position on potential allergen labeling and a better understanding of endocrine disruption and the methodology to discriminate between significant findings versus unsubstantiated and often misleading claims.

ICMAD is an active participate in the joint ICCR Industry Steering Committee and our technical representatives are currently active members in three Work Groups; namely on microbial limits, trace contaminants and safety testing methodologies. All three groups will present status reports at the ICCR-10 joint session in July.

The current interest in nanomaterial characterization, the resolution of potential product and ingredient safety concerns, denigration of well substantiated preservatives and the limitation of minute and naturally occurring trace materials continues to captivate the public. So we hope that joint efforts already under way will achieve a more fruitful consensus through collaboration between

industry and the five ICCR regulatory jurisdictions.

Finally ICMAD supports the benefits to be gained from the common characterization of safety for cosmetic ingredients and authorized substances. This is of particular importance for trace materials especially those that have been well studied and where safe harbor limits can be established to build consumer confidence on a purely scientific basis. Significant progress has been made in the past and we are hopeful that additional outcomes can be published soon on additional materials of concern.

The ICCR process has achieved some clear success in support and recognition of the ISO 22716 standard for cosmetic good manufacturing practice. This success alone has demonstrated the benefit of collaborative discussions where experience is shared between industry and the regulators to meet and resolve long-standing void. Compliance with GMP is a basic foundation for manufacturing and helps to assure product safety and trust for our consumers worldwide.

Additionally the unified position on the benefits and the need for product preservation

recently expressed and now published as an ICCR-9 outcome continues to demonstrate the public benefit of collaborative expertise regarding consumer health and safety. ICMAD and industry at large strongly support these very worthwhile efforts.

In conclusion ICMAD is committed to continued participation and support of the ICCR process. And we look forward to upcoming ICCR-10 industry caucus during joint meetings of the regulators in Bethesda, Maryland.

ICMAD is also on record in its support for open processes, timely publication of official ICCR outcomes, and a wider international outreach to include new jurisdictions where market significance and a broader engagement would be beneficial on a global basis.

We appreciate the efforts of all ICCR participants and thank you for the opportunity to provide these comments during this FDA public hearing today.

Thank you.

DR. KATZ: Our next speaker will be David

Steinberg.

MR. STEINBERG: First I want to thank Linda and the FDA for giving me this opportunity to speak to you. In February of 1969 I walked into a laboratory and for the first time I was exposed to the incredible chemistry and the mystical things that happen when you mix chemicals together to make consumer products called cosmetics. It was really fascinating. And the person who was in charge of the laboratory promptly said I'm going to teach you in the morning how to put dirt onto your skin and I'm going to teach you in the afternoon how to remove the dirt from your skin.

Now he was being a little sarcastic but in reality this is exactly what cosmetics do. We now call them leave-on products and we call them rinse-off products. We are putting things onto the skin; we are washing them off. We are putting things onto our hair; we are washing them off. It is really simple. And from this concept which we have all learned for all these years we define the efficacy of cosmetics, the claims that we make. But also we define the safety. And if you look at the different rules of the

different member countries of ICCR you will see such things as colors that are restricted for rinse-off product use only or preservatives which are prohibited for leave-on products and things like this.

So today I want to just change everyone's thinking and introduce a different concept. There should be a third category what we apply to the nail. I'm not saying anything else, just the nail. And why? Because the nail is very, very hard protein that is very, very strongly bound and cross linked. It has no nerve endings; it has no blood vessels; it doesn't scream when you clip your nails in the morning. It is totally different. The safety of what you put in the nail is totally different than what you put on any other part of your body. Nothing penetrates the nail.

If you can come up with something that penetrates the nail and gets to the nail bed I will promise you two things. One is I will personally nominate you for the Nobel Prize in medicine because we will be able to cure nail fungus. And the second is I will make you very, very wealthy. There is a huge demand for this. We just can't get anything past

the nail. It doesn't allow things to go through; therefore, we don't have safety concerns of what we put on the nail.

Now to give you some idea I'm going to reference the FDA, not the cosmetic branch, I'm going to reference the drug branch and they approved an anti-fungal nail polish; it is a prescription drug. It is called Penlac. The directions are to apply it every day for at least ten months to a year. And the success rate is terrible. Of six major trials what was reported was that the chances of a cure for nail fungus using this approved drug for this purpose are very low.

If we could penetrate the nail we would be successful. The major drug that cures nail fungus is an ingested drug which has some really nasty side effects. So we know, the drug people know we can't penetrate the nail.

So what does this mean, we need to judge the safety of products applied to the nail totally different than the way we judge other leave-on product or even rinse-off products. We really can't injure

yourself by applying it to the nail.

So what I propose is that having this category we should allow any color to be put on the nail. The major nail products are nail polishes and think of the beautiful different colors we could put on if we didn't have this restriction. Are people using these? Yes. Are they legal? No. They should be. There is no safety issue of putting a hair dye color onto the nails if it is hair dye only or a fabric dye onto the nail because it will not penetrate the nail. It won't stain the nail, it just lies there until you remove it.

So we should have no questions about what we apply to the nail. And this holds true for all the other chemicals that we put on the nail such as nail hardeners. These are principally made from the hydrated form of formaldehyde gas. They react almost instantaneously to the keratin on the nail to make the nail harder. It was discovered after World War II by teenagers who had to take biology in high school and one of the things we had to do was dissect a frog. And all the boys teased the girls; stick your fingers

and pull the frog out of the formaldehyde solution so we can dissect it. And the girl did it and she came into school the next day and said look at my nails before and after. And that was how we discovered that dilute solutions of formaldehyde harden and make the nails more attractive. So yes we can do this. Was there any injury? No.

What about the artificial nails that we put together, these are polymers that are then attached with a glue. Is there any safety issue with the glue? Yes, if you put it on your skin. Yes, if you put it on your eyelashes to put artificial eyelashes on your eye; but not for nails. There is no problem when you put it on for nails.

With that I would have a major caveat that all nail products should have this warning and the warning should say avoid contact with the skin and the cuticle. If this occurs, remove it immediately. That is the only part of the whole picture of the nail which is living, the cuticle and the skin around it.

I was asked this question by the European Union when we were talking about some of the new types

of nail polishes and they said what happens with the nail polish if it gets on your skin before it is polymerized to form the nail gels which are so popular today. I said I don't know about the Europeans but most women in the United States don't like to see nail polish on their skin, they remove it immediately and these gels are extremely hydrophobic, the ball up immediately so it isn't a question. So I think this warning is a very important one, if it comes in contact with your cuticle, if it comes in contact with the skin remove it. Otherwise it is perfectly safe.

So I think the ICCR should consider this concept. It is very important because it will do two things. First it will allow more freedom to the consumer for their choices. But the second thing is it will free up regulators' time and effort for issues that have no safety questions and allow them to use this time and money for the important safety questions.

And I thank you.

DR. KATZ: Last speaker is actually not here but the statement will be read by Rosemary Cook. And

the speaker is Cecilia Guido-Spano and again Rosemary Cook will read the statement.

MS. COOK: I purchase skin care products from doctors' offices or aestheticians. They usually carry their own line of merchandise. The labels identify the provider’s name but not the labs where the products were made. So we, the patients, don't know if the labs are in violation of industry guidelines.

A mandatory policy requiring physicians and others involved in this line of work to add the lab name as well as the ingredients would be welcome. All these products should also be regulated by the FDA.

Cecilia Guido-Spano.

DR. KATZ: That brings us to the end of our meeting.

I'd like to thank everyone for coming today; speakers for making their presentations. And I'd also like to thank some of the FDA staff who helped to make this day a success. I'm going to go alphabetically and I'm reading the list so I don't forget anyone. Robeena Aziz, Adrien Choice, Robert Collins, Anthony Ellis, David Hanley, Jon Hicks, Synthia Jenkins, John

Misock, Phillip Moulden, Tiona Shackleford, and Juanita Yates.

Finally I'd like to thank Rosemary Cook for all of her assistance as well as Stan Milstein from my staff as well.

So thank you very much. And thank you all for coming. And for those of you again who are not FDA employees, people will escort you out towards the lobby as you leave.

Thank you.

(WHEREUPON, the public meeting concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, MICHAEL FARKAS, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was recorded by me and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition 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.

MICHAEL FARKAS
Notary Public in and for the
STATE OF MARYLAND

CERTIFICATE OF TRANSCRIPTION

I, CHERYL LaSELLE, hereby certify that I am not the Court Reporter who reported the following proceeding and that I have typed the transcript of this proceeding using the Court Reporter's notes and recordings. The foregoing/attached transcript is a true, correct, and complete transcription of said proceeding.

Date CHERYL LaSELLE
Transcriptionist