Preparation for the 2014 ICCR Meeting 06-04-2014

U.S. FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING

PREPARATION FOR THE 2014 INTERNATIONAL COOPERATION ON COSMETICS REGULATION (ICCR) MEETING

Wednesday, June 4, 2014

Location:

Center for Food Safety and Applied Nutrition

5100 Paint Branch Parkway

Wiley Auditorium

College Park, Maryland 20740

S P E A K E R S

Aryenish Birdie
Physicians Committee for Responsible Medicine

Rosemary Cook, MBA
Office of Cosmetics and Colors
Center for Food Safety and Applied Nutrition, FDA

Vicki Katrinak
American Anti-Vivisection Society

Linda M. Katz, MD
Director
Office of Cosmetics and Colors
Center for Food Safety and Applied Nutrition, FDA

Tonya Kemp
Personal Care Products Council

T A B L E O F C O N T E N T S

T A B L E O F C O N T E N T S

(Continued)

P R O C E E D I N G S

DR. KATZ: Good afternoon. I'm Linda Katz, and I'm the Director for the Office of Cosmetics and Colors. We're going to go ahead and get started since it's a few minutes after 2:00. I am told that there is no one out there waiting to get in, so we can begin promptly.

I would like to welcome everybody to this afternoon's public meeting in preparation for the 2014 International Cooperation on Cosmetics Regulation Meeting. The meeting itself will be held in July in Ottawa, Canada, and I will give you the dates during the course of my presentation.

Before I begin my presentation, what I would like to do is to run through some housekeeping: if you need to use the restroom, someone will guide you as to where the men's and women's restrooms are. When it's time to leave, you will need to exit out of the building itself. If you have any cards or IDs that have been printed up for you, please remember to turn those in. As I'm looking around the room, it looks like everyone just has a sign-in placard rather than

the plastic ones themselves.

Transcriptions will be available, and they can be viewed at the Division of Dockets Management, HFA-305. A transcript will also be available in either hard copy or on CD-ROM after submission of a Freedom of Information request. And if you refer to the *Federal Register* notification, the address itself is available there.

And if anybody has a cell phone, please either silence it or turn it off now since it's very disruptive having the cell phones go off during the middle of presentations.

So I'm going to go ahead and begin. What I will do today is discuss ICCR, which is the International Cooperation on Cosmetics Regulation: describe a little bit about the purpose and process, summarize what happened in ICCR-7, giving you its outcomes, and talk about some of the upcoming issues for ICCR-8.

Well, where did ICCR start and why? I will talk a little bit about the history of ICCR. To do this, let me go back to the FDA Policy on

International Harmonization, which was published in the *Federal Register* -- and the *Federal Register* notification is listed on this slide -- on October 11, 1995. At that time, the international policy discussed the overarching goals, which included to facilitate international trade and to promote mutual understanding, facilitate the exchange of scientific and regulatory knowledge with foreign government officials -- that is, to have transparency to the extent permitted by law -- accept equivalent standards, compliance activities, and enforcement programs of other countries if such programs meet FDA's level of public health protection, and to attempt to avoid the lowering of public health protections afforded by U.S. law, in other words, prevent downward harmonization.

ICCR was established in 2006 and its first meeting was in 2007. ICCR actually developed as a result of CHIC. For those of you who may have been around in the cosmetic world for a long time, you may remember CHIC, which was the Cosmetic Harmonization and International Cooperation that occurred in the

1990s. This was a quadrilateral meeting that was held on a yearly basis with individuals from the same members that we have in ICCR, Canada, representatives from the EU, Japan, and the United States.

In 2006, after meeting in Canada for the last time as CHIC, the members of CHIC decided that it wasn't really established to do what we wanted it to do. Therefore, we needed to go further to try to be able to meet the goals of each of our respective jurisdictions. As a result, terms of reference were established where we agreed that we would have a voluntary consensus model. We took some of the precedents from ICH, the ICH GHTF, to develop some of the terms of reference. We had integral input from our industry trade associations and partners in order for them to play a role, which we felt was critical to try to make our goals go forward.

ICCR, as you can see, has been occurring since 2007, and what I describe on this slide are really the locations where we've had meetings since that time. As you'll notice, we rotate every year, and we've gone through two complete cycles when we

finish up in ICCR-8 in Ottawa, Canada, this year.

ICCR's work process is that we have an annual meeting and interim teleconferences. We have agreed at least to meet quarterly via teleconferences, sometimes more frequently as needed. The meeting venue, as I said, rotates amongst the four regions, that there is notice of the annual meetings, and draft guidelines are announced publicly to allow for stakeholder comments. In the U.S., we publish these in our *Federal Register*, and we post the information as well on our website. The hosting country or region chairs the ICCR meeting and provides the Secretariat and the Secretariat functions. The ICCR may also charter subsidiary working groups. I'll talk about some of these working groups that have been established during the course of the ICCR meetings themselves.

The meeting structure is that usually on the first day the regulators only meet, to discuss information that's relevant to regulators only. On the second day, we have a regulator and industry meeting; on the third day, a regulator meeting to

adopt the findings of the meeting and describe our outcomes and prepare any press releases.

There is also a stakeholder open session which is usually held on Day Two. On some occasions, it's been held on Day Three if the meeting has gone over to 4 days. During that open session, there are stakeholder presentations. The outcomes of the ICCR meeting are posted to each regulator website and a reconciled press release is also done. This is to allow for transparency, to describe what our deliverables have been, and once the documents have been accepted during the ICCR meetings, they will be posted.

In the past 2 years, we have been working on our ICCRnet.org website. We are hopeful that coming this year that website will be up and running, which will make it easier for everybody to find information in one place. Each of us will link to that website.

So let me go through and describe what happened at ICCR-7, which was held in Tokyo from July 8th through July 10th last year. The structure itself has been described. The agenda basically was

as follows: we discussed alternatives to animal testing, nanotechnology, trace impurities, *in silico* prediction models for safety assessment, endocrine disrupters, and allergens.

With regard to alternative test methods, the regulators received an update on International Cooperation on Alternative Test Methods, which we refer to as ICATM, activities. The industry report entitled, "Inventory of Validated Alternatives to Animal Testing Worked on by ICATM Partners, Applicable for Cosmetic Products and Their Ingredients in All ICCR Regions," was accepted and was posted. The Annex to the report was discussed and was accepted with an agreement to update on a semi-annual basis. Basically, the ICATM report itself and the Annex contains tables that include the updated animal alternative tests that have been validated and accepted by the VAMs of the corresponding regions.

With regard to nanomaterials, the document "Characterization of Nanomaterials III -- Insolubility, Biopersistence and Size Measurement in Complex Media" was presented and discussed. The

Characterization of Nanomaterials Working Group agreed to continue its work and to develop a survey of scientific information that will be conducted between ICCR-8 and ICCR-9. It is anticipated that the results of the survey will be presented at ICCR-9 since it's ongoing work right now.

The "Safety Approaches to Nanomaterials in Cosmetics" was accepted and was posted on each jurisdiction's website.

With regard to trace impurities, the document on lead was accepted. It's still undergoing some editorial changes, and we anticipate that it should be published and posted to the websites within the next several months.

The documents on mercury and 1,4-dioxane are in the process of undergoing continued review.

With regard to *in silico* prediction models for cosmetic safety assessment, the Working Group presented its progress report at the Regulators-Industry Dialogue Meeting. They also agreed to work and to draft a White Paper, which was drafted, on *in silico* capability in relation to potential

applications in the assessment of cosmetic ingredients, highlighting any data or knowledge gaps, and this will be presented at ICCR-8.

With regard to endocrine disruptors, industry agreed to provide additional information and a proposal for future discussion if it is to be continued as an agenda item.

With regard to allergens, a working group was formed. The working group presented a progress report at the Regulator-Industry Dialogue Meeting and intends to deliver a draft White Paper at ICCR-8.

Now, with regard to the involvement of interested parties in ICCR, regulators finalized the criteria to allow interested parties to submit detailed proposals for work items for ICCR members' consideration. Interested parties include any new members, meaning new member countries, and their international trade associations are considered in tandem with the new regulators -- so in other words, it would be the international partner for the regulators of the particular jurisdiction -- non-governmental organizations, and academia.

With regard to participation, in last year's meeting, participants, or observers, of regulators and industry representatives from Brazil and People's Republic of China did participate in Japan. The open session that was held for stakeholders had presentations made on nanotechnology, cosmetic product safety, alternatives to animal testing, and endocrine disruptors.

The ICCR Steering Committee reviewed the stakeholder proposals for consistency with objectives, and scope for the terms of reference for future discussion in ICCR. Other new work items may be submitted at any time to ICCR members. We invite you to do so if there are additional work items that you would like to submit to us.

Regarding ICCR-8, Canada is to host this year, and the meeting will be held from July 8th through 10th, in Ottawa, Canada. During this past year, Canada has been responsible for quarterly interim teleconferences and for other teleconferences as needed.

The agenda itself is similar to last year's

agenda. We again are going through and discuss alternatives to animal testing, looking for any further updates for validated models; discussion of nanotechnology and the outstanding reports; discussion of trace impurities documents; *in silico* models; and, as I mentioned earlier, the White Paper will be presented at this upcoming meeting. With regard to allergens, the White Paper will also be presented at this meeting. If there are any new proposed agenda items that come as a result of this meeting or through other contacts with Health Canada, they will be discussed at the meeting itself.

So I thank you very much for your attention. I would like to continue on now with our public comments.

We have listed those who have asked to speak in alphabetical order. I will call on each of them. All three speakers who are here today have up to 10 minutes to speak. There are two representatives that could not attend, but they have forwarded us their comments, and those will be read into the record by Rosemary Cook. When we get to that portion, I will

let you know who they are.

So we'll begin with Ms. Aryenish Birdie from the Physicians Committee for Responsible Medicine.

MS. BIRDIE: Hi. My name is Aryenish Birdie. I am speaking on behalf of the Physicians Committee for Responsible Medicine. We promote human relevant test methods for better ethics and public health protection. We have a membership of over 150,000 people including over 12,000 physicians.

And today I am speaking on the limitations of focusing only on using validated alternative methods for cosmetics in the four ICCR regions.

So let me begin by sharing the ultimate goal I think that is shared by many people in this room, which is a full ban on animal testing for cosmetics. The global consumer has said time and time again, we see in polls, that ethics is important and that they don't want animals dying for their cosmetics. We realize that testing method harmonization isn't the goal of ICCR, but we believe that it is important for the agencies within ICCR to harmonize their policy approaches on animal testing to take into account the

global desire of consumers.

And since the last meeting I presented at last year, there have been a number of legislative updates, including Vietnam taking steps towards non-animal testing, the Brazilian state of Sao Paulo has banned animal testing, India has banned animal testing, and it is on track to considering a marketing ban similar to the EU, and even China, where animal testing is mandatory, they are taking steps to reevaluate their policy.

So let me say a little bit more about the validated alternatives. I've heard multiple times in this forum and in others that using validated alternatives is the only way forward, and there are a number of problems from our perspective on this approach, so I want to enumerate them.

Firstly, animal tests have never been validated, they have never undergone the strict validation process that the non-animal test methods are currently undergoing, so that should be kept in mind I think as we move forward.

A full validation process is prohibitively

slow and costly, and because of this, a number of appropriate test methods haven't been formally validated, and I'll speak a little bit more about this on the next slide. But I guess another way of saying that is relying only on validated alternatives limits the number of tools available, and without better harmonization methods, that may be valid in one region but not another, and this is a major disadvantage for developers. And again it doesn't take into account the EU situation, where there is a full testing and marketing ban on animal testing.

So I wanted to speak a little about the list that was mentioned in the previous presentation. The methods developed or the methods listed on this table are only OECD-validated methods, and we don't need to rely exclusively on OECD guidelines for the testing of cosmetics. Other methods may be valid but aren't listed, such as the cell transformation assays -- or, I'm sorry, the in vitro cell transformation assays and the keratin skin sensitization assay. Those are just a couple examples of a whole host of other assays.

So despite being published less than a year

ago, 2013, there are a number of other methods that could be listed, and because of this, we just think that moving away from exclusively OECD guidelines would be a good step forward.

So I wanted to offer a few solutions, one you probably can guess. ICCR countries should be open to reviewing and accepting data from non-OECD methods. When using reference to validated test methods, other terms, such "valid" or "scientifically appropriate" or "fit for purpose" are all terms that could be used that don't have the stigma of validation or validated test methods.

And in fact a recent cosmetics design article just less than 2 weeks ago said that TTIP, the Transatlantic Trade Investment Partnership, which is the free trade agreement being hammered out between the U.S. and the EU, has said that it can facilitate a unity of standards by strengthening the harmonization work carried out at the international level under ICCR. So I think this is a ripe opportunity and perfect time to make these changes.

And that's it. Thank you.

DR. KATZ: Thank you. Our next speaker is Vicki Katrinak, from the American Anti-Vivisection Society.

MS. KATRINAK: Good afternoon, and thank you for the opportunity to present comments in preparation for the ICCR meeting taking place in Ottawa. My name is Vicki Katrinak, and I am the Policy Analyst at the American Anti-Vivisection Society. We were founded in 1883. We're the first non-profit animal advocacy and educational organization in the U.S. working to protect animals used in research, testing, and education. AAVS is also the current Chair of the Coalition for Consumer Information on Cosmetics, and I serve as the Administrator for this Coalition.

CCIC is comprised of leading animal protection organizations in the United States and Canada, representing over 10 million members. CCIC runs the Leaping Bunny Program in both countries as a service to those members and others who are concerned about animal testing. The Leaping Bunny Program certifies cosmetic and household product companies as cruelty-free if they are not engaged in any new animal

testing of products, formulations, or ingredients. We currently have over 500 certified companies in the U.S. and Canada.

AAVS is very encouraged that the U.S., Canadian, European, and Japanese regulators continue to work together to ensure that cosmetic regulations are consistent. This uniformity will ease the burden felt by companies selling in these countries as they navigate the regulatory landscape of each country. AAVS is particularly pleased to see that the development of and gaining regulatory acceptance for non-animal alternative test methods remains an important objective at the ICCR meetings.

ICCR's first meeting took place in September 2007. As an organization looking to end the use of animals to test cosmetics, it is gratifying to look back and note how much has changed since that time. The EU's ban on the use of animals to test cosmetic products and ingredients and prohibition on selling products that were tested using animal models has now gone into effect without any delay.

Israel passed a similar ban to the EU, and

India has now banned animal testing for cosmetic products and ingredients.

In the United States, legislators have introduced the Humane Cosmetics Act, legislation to prohibit the use of animals to test cosmetic products and ingredients and also phase out the sale of products that have been tested in animals. So far, 126 companies certified by the Leaping Bunny Program have endorsed this legislation.

China has also begun making progress toward acceptance of non-animal alternative methods by phasing out its mandatory animal tests for many products.

Although consumer demand has clearly played an important role in pushing this issue forward, dedicated efforts by industry and regulators alike have clearly helped to make the world without animal testing for cosmetics a real possibility.

AAVS is encouraged to see that in last year's ICCR meeting, China and Brazil were invited to participate as observers in the process. Clearly, these countries and the regulations they enforce are

important to the international cosmetics industry. The discrepancies between their laws and those of other ICCR member countries are significant and present hurdles to companies that wish to avoid animal testing. We urge ICCR member countries to continue pressing for further harmonization on an international level. It will not only help companies to increase business but also move the world closer to an end of animal testing for cosmetic products, which is a responsible and scientifically appropriate regulatory position.

In conclusion, I would just like to reiterate our appreciation of efforts to harmonize cosmetic regulations, and we strongly support any efforts to further reduce or eliminate the need for animal tests and to include other countries' participation in these efforts.

Thank you so much for your time.

DR. KATZ: Thank you.

Our next speaker is Tonya Kemp, from Personal Care Products Council.

MS. KEMP: Thank you. On behalf of the

Personal Care Products Council, I am pleased to have this opportunity to emphasize our industry's strong support for the ICCR process. We would like to express our appreciation to FDA and the other participating regulators from Europe, Japan, Canada, Brazil, and China, for their participation and support of the ICCR process. We believe the ICCR has been a beneficial forum for the exchange of information and regulatory alignment between important markets for cosmetics and personal care products.

PCPC is the leading national trade association representing the global cosmetic and personal care products industry. It was founded in 1894 and has more than 600 member companies, those that represent both manufacturing, distribution, and suppliers. Our members represent some of the most well-known products and product categories in the world and include many medium and smaller sized companies.

For more than 100 years, regulators and policymakers have relied on our organization to deliver honest, credible, and accurate scientific

information about cosmetics and personal care products. We take this responsibility very seriously and are pleased to represent our industry in the ICCR.

We are a truly global industry, which are dependent on open markets and transparent, consistent regulatory environments around the world. Our member companies continually strive to uphold and surpass the most stringent regulatory and product integrity standards worldwide, and provide our consumers with safe, innovative, and high quality cosmetic and personal care products. Most of our ingredients are globally sourced.

International trade is a critical component to the success of our industry and significantly contributes to our ability to expand manufacturing and employment as well as to support other industries, such as advertising, packaging, and transportation. The globalization of our industry also promotes continual technological innovation, which contributes significantly to the application of scientific advancement and benefits consumers around the world.

For all these reasons, the Personal Care

Products Council is actively engaged in international efforts to align global regulatory standards for consumer products, eliminate trade barriers, and ensure a level playing field for member companies while at the same time reinforcing consumer confidence in product safety. Initiatives such as the Trans Pacific Partnership, and the Transatlantic Trade and Investment Partnership, and other international trade and regulatory fora and scientific exchanges support these objectives.

The stated mission of ICCR, "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 a globalized environment.

We firmly believe that the ICCR serves as an important forum for alignment of regulations, policies, and guidelines affecting our industry and as a source for other countries looking to model their regulatory approaches around such common guidelines.

As the ICCR is now completing its eighth cycle, it is important to acknowledge the important

decisions that have been taken by regulators in the process already, including the support for a common standard for cosmetic GMPs; surveys of nanotechnology as it pertains to cosmetic products; principles of cosmetic product safety assessment; and promotion of validated methods for alternatives to animal testing.

We believe the ICCR has an especially important role in considering common, science-based policies for the treatment of trace substances which can sometimes be found in cosmetic products and ingredients, many of them arising from natural sources.

For example, over the past several years, the ICCR Traces Working Group, consisting of scientists and regulatory experts from the four ICCR jurisdictions, has recommended Principles of Handling Trace Materials, and this was endorsed by the ICCR regulators. The ICCR Traces Working Group has also developed recommendations for acceptable trace levels of lead, 1,4-dioxane, and mercury in cosmetics. We are hopeful that at the ICCR-8 meeting in Ottawa this summer regulators will endorse a safety standard for

traces of lead, and that final decisions on 1,4-dioxane and mercury will soon follow.

Our industry fully supports the formal expansion of ICCR to other countries. We believe that China and Brazil, which have served as observers, should become full members of the process with all the rights and responsibilities this entails and that other countries should be allowed to join as well. We look forward to receiving additional information about the criteria that the founding members of ICCR will use to consider new countries to be added to the process and the procedures for observer countries to graduate to full membership.

We understand that the expansion of ICCR to other members means that our efforts must become even more efficient and that the ICCR processes and procedures must become even more effective. We look forward to working with FDA and other regulators to enhance the ICCR process in the months and years ahead.

Thank you.

DR. KATZ: Thank you.

Next I will call Rosemary Cook to read into the record two statements, the first for Cruelty Free International and New England Anti-Vivisection Society, and the second will be from the Independent Cosmetic Manufacturers and Distributors.

MS. COOK: Good afternoon. The first set of comments was submitted by the Cruelty Free International and New England Anti-Vivisection Society. This is a letter sent to the attention of, "Leslie Kux, Assistant Commissioner for Policy, Food and Drug Administration, U.S. Department of Health and Human Services, May 27, 2014, RE: Comments for June 4, 2014, International Cooperation on Cosmetics Regulation (ICCR) Preparation for ICCR-8 Meeting."

"Dear Ms. Kux and FDA representatives to the ICCR,

"Cruelty Free International and the New England Anti-Vivisection Society are pleased to offer these comments on the International Cooperation on Cosmetics Regulation (ICCR) in preparation for the July ICCR-8 Meeting in Canada. As you may be aware, Cruelty Free International is the leading organization

focused specifically on ending animal testing for cosmetics and consumer products. We have offices in the United States, Brazil, London, and Singapore, and have partnership organizations in all the major cosmetics markets, including India, Korea, Vietnam, and Australasia.

The New England Anti-Vivisection Society, NEAVS, founded in 1895, is a U.S. Boston-based national animal advocacy organization dedicated to ending the use of animals in research, testing, and science education. Through research, outreach, education, legislation, and policy change, NEAVS advocates for replacing animals with modern alternatives that are ethically, humanely, and scientifically superior.

While there is a global trend toward ending the use of animal testing for cosmetics, different countries are at different stages of the process. We believe that it is in the interest of consumers, regulatory agencies, and the national cosmetics industries to have broadly similar safety testing regulations. Harmonizing regulations would enable

each product to have one safety dossier that would be universally accepted. With alternatives to animal testing widely available, most consumers no longer want cosmetics which have been tested using methods involving animal suffering. Responding to this consumer view, many companies have been moving rapidly to end animal testing.

Most of the tests usually carried out on animals for cosmetics ingredients have alternatives at similar or lower costs which have been approved by the OECD as official test guidelines. The tests have comparable or higher predictive value for effects on humans than the animal tests that they replace, many of which themselves have a poor record in prediction and have not been accepted -- subjected -- excuse me -- to the rigorous validation process that alternative tests undergo.

In addition, evidence demonstrates that alternatives have fewer negative impacts on the environment. Animal use and disposal and the associated use of chemicals and supplies contribute to pollution as well as public health concerns. Animal

testing involves the production, use, and/or discarding of materials and supplies, such as food, caging, including disposable caging, chemicals, excrement, bedding, waste feed, needles, syringes, and other materials. The use of alternatives, therefore, also contributes to industry's sustainability measures, a growing and priority concern of consumers looking for more environmentally friendly products. More information on the environmental harms of animal testing is available from NEAVS by mailing info@NEAVS.org.

For some animal tests that have been used in the past or in other contexts, alternatives are still being developed or validated, but these animal tests are generally not now used for cosmetics. For example, the carcinogenicity tests on animals is not normally used for cosmetics at all, since it takes 2 years and has a less than 50 percent likelihood of correctly predicting human effects, essentially no better than the chance of a coin toss.

Cruelty Free International has produced a detailed analysis of the scientific status of every

test. The report "Meeting the Global Challenge: A Guide to Assessing the Safety of Cosmetics Without Using Animals" is available by request from Cruelty Free International by e-mailing usa@crueltyfreeinternational.org.

Clearly, Cruelty Free International and the New England Anti-Vivisection Society encourage a constructive discussion at the ICCR on all of the participating members moving toward a ban on animal testing for cosmetics similar to that of the European Union.

When the concept of a harmonized global ban is discussed three issues typically arise.

The first is the interaction with REACH -- R-E-A-C-H -- and with other testing environments; for example, if a company has an ingredient that is used in both cosmetics and for other purposes. In some cases, a manufacturer may not know initially whether its main market is cosmetics or some other purpose. In such cases, each country would need to decide how to respond. Generally, there are three possibilities.

1) If the ingredient has been tested on

animals, it can't be used for cosmetics. [This is our preferred choice.]

2) Any animal tests conducted cannot be submitted to determine safety of an ingredient used in cosmetics. However, non-animal tests for the same product may be submitted even if the animal tests have already been conducted.

3) Animal testing data can be used if it was done in accordance with a separate testing regime not associated with testing for cosmetic purpose.

In the European Union, products cannot be marketed if an ingredient has been tested on animals primarily for cosmetic purposes. If tests for an ingredient mainly used for non-cosmetics purposes are carried out under a non-cosmetics testing regime, they are not considered by the European authorities to breach the ban even if the ingredient is also used for cosmetics.

The second issue is innovation. One of the frequently stated concerns of industry is that banning animal tests for cosmetics could impede the introduction of new innovative ingredients that would

develop the market. It is our understanding that with Cosmetics Europe, only 3 to 5 percent of new cosmetics each year actually have new ingredients, and a significant number of those have already been proved safe by utilizing modern, non-animal methods or under other testing regimens -- regimes -- excuse me -- like REACH.

Ultimately, a balance between consumer desire for an end to animal testing for cosmetics and the desire for innovation must be reached. Additional innovation in development and validation of non-animal tests will be key in striking this balance. Indeed, in Europe, the drive for additional non-animal alternatives was spurred by the impending ban. Moreover, as non-animal tests are often cheaper, faster, and more accurate than the animal tests they replace, we are confident that innovation and the further phasing out of animal tests can be achieved concomitantly.

The third issue is exports to China, as it is the only country that still requires animal tests for imports. However, China is ending the animal

testing requirement for products produced domestically this June. China's cosmetics industry likewise has a vested interest in moving away from animal tests in order to achieve future export ambitions in a global marketplace that is increasingly turning away from animal-tested cosmetics. It is anticipated that most of the OECD Test Guidelines for Alternatives to Animal Testing will be introduced and accepted in the next few years and that the animal testing requirement for imported products will follow shortly thereafter.

The full EU ban has now been in effect for a little over a year and there has already been a ripple effect. In early 2013, India became the first country in Asia to announce a ban animal testing for cosmetics. The state of Sao Paulo Brazil has now banned animal testing for cosmetics and countrywide ban within the next 5 years is being discussed. In May, Vietnam announced that it will ban the Draize Test and training in use of other alternatives is underway. Korea is also making strides towards ending cosmetics testing on animals.

In the United States, the recent

introduction of the federal Humane Cosmetics Act H.R. 4148, which now has 45 co-sponsors and the list is growing, and the tremendous bipartisan support in the California Senate for SJR 22, the Cruelty Free Cosmetics Resolution, shows that legislators are listening to the American public, which, polls show, largely support ending cosmetics testing on animals.

It is our hope is that in light of these developments and the increasing concern about animal testing around the world, that the ICCR will have a robust discussion on the steps needed to finally ending animal testing. At the meeting in July, we ask that at minimum the following issues be considered.

1) Bans on the testing on finished products. This is a practice that has practically died out with most companies, indicating that they do not need to test finished products. While the number of animals used in final product testing is assumed to be quite low, a ban on the testing of finished cosmetic products would be a step in the right direction and would demonstrate that regulators are beginning to respond to consumer interests.

2) Mandates on the use of scientifically validated alternatives. Where an alternative has been validated either in the U.S., Japan, or Canada, regulators should require that the alternative be used in lieu of the animal test for that endpoint. In 2000, the State of California enacted a law that prohibits manufacturers and contract testing facilities from using animal test methods when an appropriate scientifically validated non-animal test was available. New Jersey and New York followed California's lead in 2007 and 2008 respectively with similar -- quote, unquote -- "mandated alternative" laws.

3) Deadlines for ending animal testing for cosmetics. We believe it is reasonable to phase out animal testing of ingredients primarily used in cosmetics by December 2015. Setting of a deadline creates a target for industry and allows time for industry and regulators to adapt accordingly.

Switching to alternatives to replace animal testing will ensure that the safest and most modern test methods are used and that domestic cosmetics

companies are not cut off from European and other markets due to dependence on antiquated animal tests.

We thank you for your consideration of these comments and welcome any questions you may have.

Sincerely, Monica Engebretson, North American Campaign Manager, Cruelty Free International, P.O. Box 221694, Sacramento, CA 95822. Katherine Groff, Director of Research and Investigations, New England Anti-Vivisection Society, 333 Washington Street, Suite 850, Boston, MA 02108."

The next set of comments is submitted by the Independent Cosmetic Manufacturers and Distributors.

"ICCR Public Meeting, June 4, 2014, U.S. Food and Drug Administration, College Park, Maryland 20740. Comments by Carl Geffken, Chair, ICMAD International Committee.

My name is Carl Geffken, and I am providing comments today on behalf of the Independent Cosmetic Manufacturers and Distributors. ICMAD -- or "Ickmad" (phonetic pronunciation) -- is a nonprofit cosmetic industry trade association representing about 750 mostly small to medium size companies that manufacture

and/or distribute cosmetic products, components, materials, and services in the U.S. and worldwide markets.

Recently relocated to 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. About 90 percent of our member companies are small but highly competitive businesses that compete globally for a share in our very creative cosmetic and skin care markets.

About half of our member companies have sales below $500,000 annually, while about 20 percent of members have sales above $10 million per year. A number of members are international and represent 18 different countries, although Canada is the most important -- is the most -- excuse me -- prevalent. Apologies for that.

Our members are 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 their 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 the unique requirements of the European Cosmetic Regulation and its associated markets.

The Association also sponsors both an annual FDA Workshop and a Cosmetic Technical-Regulatory Forum among its other opportunities to provide ongoing regulatory assistance and to address the many technical and safety obligations for our segment of the industry. I assure you that the Association takes all compliance responsibilities with utmost concern.

Eight years ago, the FDA invited 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 improved 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 different international jurisdictions.

From a historical perspective, in 2008, ICMAD sponsored a comprehensive consumer survey of over 2,300 individuals to better understand cosmetic ingredient labeling interpretations, and we provided data to support broad -- about 80-plus percent -- U.S. recognition of 'aqua' as a potential equivalent to the INCI -- or ‘inky’ (phonetic pronunciation) -- term 'water.' Our industry continues to experience the technical and economic burden of unique labeling differences when attempting to harmonize production for international sales, especially in the Canadian market.

While the outcome of this issue has 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, including unified acceptable trace contaminant levels, better alignment of acceptable microbiological contaminant limits, a unified position on potential allergen labeling, and a better understanding of endocrine disruption and the methodology to discriminate between significant and inappropriate testing.

The current interest in Nanomaterial characterization and the resolution of potential product safety concerns continues to captivate the public, so we hope that joint efforts already underway will achieve a more fruitful consensus through joint collaboration between the four regulatory jurisdictions, as well as the two new observer countries and their representatives.

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 for 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 2 years, and we are hopeful that outcomes can be published soon and even further progress achieved on additional materials during ICCR-8.

The ICCR process has achieved some clear success in its 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 a longstanding void. Compliance with GMP is a basic foundation for manufacturing and helps to assure product safety and trust for our consumers worldwide. We are confident that all four regulatory jurisdictions will continue to support recognition of this minimum expectation for basic GMP compliance.

In conclusion, ICMAD is committed to continued participation and support of the ICCR process, and we look forward to the upcoming ICCR-8

Industry Caucus during the joint meeting of regulators in Canada. ICMAD is also on record in its support for an open process, 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.

Thank you for the opportunity to provide my comments during this FDA public hearing today.

Sincerely, Carl Geffken, June 4, 2013," -- but I know he meant ‘14.

Thank you.

DR. KATZ: Thank you. And so adjourns our meeting. We have had all of our speakers who have requested to speak come up. As I mentioned before, transcripts will be available, and if you refer to your *Federal Register* Notice, you will be informed of how to request it.

If you have any additional information that you would like for us to have before the ICCR meeting, you are more than welcome to send it to us as well, and we can distribute that at ICCR in Ottawa.

I thank you very much for your attention.

(Whereupon, at 2:44 p.m., the FDA Public Meeting for the Preparation for the 2014 International Cooperation on Cosmetics Regulation (ICCR) Meeting was adjourned.)

CERTIFICATE OF COURT REPORTER

I, NATALIA THOMAS, the reporter before whom the foregoing hearing 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.

NATALIA THOMAS

CERTIFICATE OF TRANSCRIBER

I, DEBORAH ARBOGAST, do hereby certify that this transcript was prepared from audio to the best of my

ability.

I am neither counsel for, nor party to this action nor am I interested in the outcome of this action.

DEBORAH ARBOGAST