

**Comments to the International Cooperation on Cosmetics Regulation
Preparatory Meeting**

**by:
Campaign for Safe Cosmetics
June 18, 2008**

The Campaign for Safe Cosmetics is a coalition of public health, educational, religious, labor, women's, environmental and consumer groups working together to protect the health of consumers by securing stronger federal oversight and regulation of chemicals linked to adverse health effects in cosmetics and personal care products sold in the U.S. and globally.

These comments cover how to strengthen the process behind the International Cooperation on Cosmetics Regulation (ICCR) meetings, and the need for stronger government regulation of ingredients currently being used in cosmetics that are negatively impacting human health and environmental health. These comments include an overview of:

- The Campaign for Safe Cosmetics;
- Lack of FDA Regulation and Oversight & Shortcomings of a Self-Regulated Cosmetics Industry
- Recommendations for improving the regulation of cosmetics globally; and
- Ways in which the ICCR stakeholder involvement process can be strengthened

We appreciate efforts in the European Union, Japan and Canada toward more strictly regulating cosmetics by acknowledging that chemicals linked to cancer and birth defects don't belong in cosmetics. The U.S. has much to learn from these examples and we implore the agencies in these countries to continue to strengthen and expand their leadership on this critically important women's health and consumer health issue.

Last year we also requested that the ICCR be opened up to a broader range of stakeholders. The fact that this has not yet happened is inexcusable, given the fact that the chemicals used in personal care products end up in the bodies of nearly everyone in the population, including some at levels that may pose risks – the inclusion of organizations that advocate for public health and represent the public's interests is critical. We renew this request. We ask that the ICCR members recognize that the doors of this meeting must be opened to a broader range of stakeholders, and that a vote be held on this issue at this year's meeting.

The Campaign for Safe Cosmetics

The Campaign for Safe Cosmetics officially launched in February 2003 building on the momentum of the European Union's newly amended cosmetics directive and today is made up of close to 1,000 companies who have aligned themselves with the goals and values of the Campaign – including over 100 from outside the U.S. -- 40,000 grassroots supporters and over 150 environmental health and justice organizations that have endorsed the campaign.

In June 2004, the Campaign conducted a personal care product use survey of more than 2,300 people which showed the average adult uses 9 personal care products each day, with 126 unique chemical ingredients. More than a quarter of all women and one of every 100 men use at least 15 products daily. Among the findings of this 2004 survey are the following:

- Women and girls use an average of 12 personal care products daily
- One out of every 100 personal care products on the market contains known or probable **carcinogens**
- One of every 24 women, 4.3 million women altogether, are exposed daily to personal care product ingredients that are known or probable **reproductive and developmental toxins**, linked to impaired fertility or developmental harm for a baby in the womb or a child. These statistics do not account for exposures to phthalates that testing shows appear in an estimated three quarters of all personal care products but that, as components of fragrance, are not listed on product ingredient labels (EWG et al. 2002).
- One of every five adults are potentially exposed every day to all of the top seven carcinogenic impurities common to personal care product ingredients — hydroquinone, ethylene dioxide, 1,4-dioxane, formaldehyde, nitrosamines, PAHs, and acrylamide. The top most common impurity ranked by number of people exposed is hydroquinone, which is a potential contaminant in products used daily by 94% of all women and 69% of all men. (EWG, 2004)

Lack of FDA Regulation and Oversight & Shortcomings of a Self-Regulated Cosmetics Industry

The personal care product industry's self-policing safety panel, the Cosmetic Ingredient Review, approaches each safety assessment as if consumers are exposed to just one chemical at a time, and as if personal care products are the only source of exposure for each chemical considered. The panel is often wrong on both counts.

The combined exposure from personal care products adds to the chemical contaminants people are exposed to on a daily basis from other consumer products, food, water, air and soil. The results of this survey in combination with other studies show that people are exposed to hundreds of chemicals over the course of a day (CDC 2003, Thornton et al.

2002, EWG 2003) and these chemicals are ending up in all of us: more than 200 chemicals have been detected in people's blood, urine and breast milk and in the cord blood of newborn babies.

The industry's panel does not consider the reality of patterns of human exposures when declaring chemicals "safe as used" in cosmetics, for example:

- additive effects of exposures to multiple chemicals linked to common negative health impacts;
- the cumulative effect of exposures over a life time;
- the timing of exposure which can magnify the harm for the very young and the very old; and
- worker exposures.

Consumers shouldn't have to be worried about cancer-causing chemicals in cosmetics.

Only 10% of all breast cancers can be explained by a genetic history of the disease and more and more scientific evidence points to some of the 100,000 synthetic chemicals registered for use today as contributing to the development of breast cancer, either by altering hormone function or gene expression (Breast Cancer Fund, 2008).

Known as xenoestrogens, many synthetic agents mimic the actions of estrogens and – in the process -- disrupt the endocrine system – and hormonal processes – both of which can affect breast cancer risk.

A report by the Breast Cancer Fund links these endocrine disrupting chemicals to early puberty in girls which is linked to later life breast cancer and a whole host of other troubling negative emotional and physical consequences (Steingraber, 2007).

Many consumers believe the U.S. government regulates the \$50 billion cosmetics industry the same way it regulates food and drugs sold in this country and ensures the safety of personal care products before they are sold. Despite the industry's size, its depth and its breadth, the FDA's own website explains its limitations. According to the FDA Office of Cosmetics and Colors:

The FDA cannot require companies to {conduct} safety testing of their cosmetic products before marketing

--and--

"...a cosmetic manufacturer may use almost any raw material as a cosmetic ingredient and market the product without an approval from FDA" (FDA 1999).

The Cosmetics Ingredients Review (CIR), the industry's self-policing safety panel, falls far short of compensating for the lack of FDA oversight. Through 3 decades the CIR has reviewed only about 11% of the ingredients in products, or 1,400 out of what FDA estimates is a total of 12,500 ingredients in personal care products (FDA 2007c). This panel purportedly provides the U.S. people with a public health backstop for safety, but it operates in a vacuum of guidance from FDA when it comes to the safety of personal care products. Words on labels like natural, safe, and pure have no definition in law and no relationship to the hazard inside the packaging. Acceptable levels of risk are entirely at this panel's discretion.

Recommendations for Strengthening the Global Regulation of Cosmetics

Voluntary self-regulation of the cosmetics industry in the U.S. is not working. The U.S. needs to ramp up its protection of consumers and the EU, Canada, Japan and other world governments should strengthen and expand their existing cosmetic regulations by:

1. Requiring pre-market safety testing of all cosmetic products.
2. Instituting mandatory recalls of cosmetics containing ingredients that have not been proven safe through scientific testing and/or do not bear appropriate labels warning consumers that the product ingredients have not been substantiated for safety.
3. Restricting the use of ingredients that contains any toxic impurity or that may combine with other ingredients to form harmful impurities.
4. Requiring all Internet vendors to display a conspicuous list of ingredients of cosmetic products sold on their websites.
5. Requiring labeling of the constituent ingredients of fragrance.
6. Requiring labeling of nanomaterials in cosmetics and personal care products.
7. Working with stakeholder groups like the Campaign for Safe Cosmetics to develop a hazard-based international standard for cosmetic safety.
8. Issuing guidance on substantiating the safety of ingredients used to formulate cosmetics.
9. Requiring cosmetics manufacturers make all existing safety data available to government agencies and to consumers.
10. Investing in Green chemistry solutions to replace toxic chemicals used in cosmetics with safe alternatives.
11. Requiring testing of personal care products for their estrogenic activity – especially products used by and on children.
12. Erring on the side of safety and adopt a precautionary approach toward allowing the use of emerging chemicals of concern in cosmetics.

Recommendations for Strengthening the ICCR Process

The Campaign for Safe Cosmetics brings other concerns regarding some of the stated goals and processes of ICCR as well as specific proposals for strengthening the processes of the ICCR.

First, we implore this body to focus its energies on identifying ways to remove obstacles to more effectively regulating cosmetics, as opposed to working to remove safe cosmetics regulations themselves.

Second, the ICCR should build the most broad based and effective feedback loop possible to support the upcoming Brussels meeting by:

- Including women's health, environmental health and other advocacy organizations at the table for all stakeholder convenings related to the activities of the ICCR;
- Soliciting input directly from these and other stakeholders, as opposed to using the industry trade associations as the intermediary for communications;
- Inviting stakeholder groups like the Campaign for Safe Cosmetics to "enter into constructive dialogue with ICCR members to provide feedback and advice on priority actions and directions for future work"— a function currently described as the sole jurisdiction of "industry trade associations."
- Inviting a broad spectrum of stakeholders to serve on working groups responsible for developing proposed guidelines and policy statements for adoption by the members.

And finally, the ICCR process should bring participating governments up to the highest standard possible for regulating cosmetics, not weaken existing safe cosmetics standards.

We hope to see new commitment from ICCR, FDA and the cosmetics industry to the important children's health, women's health and consumer health issue represented by personal care products.

References

Breast Cancer Fund, Gray J. ed. (2008) *State of the Evidence 2008: The Connection Between Breast Cancer and the Environment*. March 2008. Available online at <http://www.breastcancerfund.org/site/pp.asp?c=kwKXLdPaE&b=206137>

Centers for Disease Control and Prevention (CDC) (2003). Second National Report on Human Exposure to Environmental Chemicals. Available online at <http://www.cdc.gov/exposurereport/2nd/>.

Environmental Working Group (EWG), Healthcare Without Harm, and Womens Voices for the Earth (Houlihan, Brody, and Schwan) (2002). Not Too Pretty. Phthalates, beauty products, and the FDA. July 2002. Available online at <http://www.ewg.org/issues/cosmetics> and <http://www.safecosmetics.org>.

Environmental Working Group (2003). Body Burden. Pollution in People. January 2003. Available online at <http://www.ewg.org/reports/bodyburden/index.php>.

Environmental Working Group (2006) Impurities of Concern in Personal Care Products (as of Dec 2006). <http://skindeep.ewg.org/reports/node/43>. Accessed June 18, 2008.

FDA (U.S. Food and Drug Administration). 2007c. Compliance Program Guidance Manual. Program 7329.001. Chapter 29 – Colors and Cosmetics Technology. Available for download at <http://www.cfsan.fda.gov/~comm/cp-toc.html>. Accessed May 11 2008.

Steingraber S. 2007. The Falling Age of Puberty: What we know, what we need to know. Breast Cancer Fund. August 2007.
<http://www.breastcancerfund.org/site/pp.asp?c=kwKXLdPaE&b=3266509>

Thornton JW, McCally M, Houlihan J. (2002). Biomonitoring of industrial pollutants: health and policy implications of the chemical body burden. *Public Health Rep.* 2002 Jul-Aug;117(4):315-23.