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Comments: Public Meeting on
"International Cooperation on Cosmetics Regulations (ICCR) –
Preparations for ICCR Meetings in Washington, DC"

by:
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Before the
U.S. Food and Drug Administration
Thursday, June 19, 2008

The Environmental Working Group (EWG) is a nonprofit research and advocacy organization based in Washington, DC and Oakland, California, and a founding member of the Campaign for Safe Cosmetics. We appreciate the International Cooperation on Cosmetics Regulations (ICCR) members' interest in, and commitment to "maintain[ing] the highest level of global consumer protection." Unfortunately, the cosmetics industry has enjoyed a largely unwatched and unregulated status in the U.S. that raises serious concerns for public health, and the ICCR process has done little to fill these significant gaps.

The comments presented here are modified from testimony prepared and delivered by EWG on May 14, 2008 before the U.S. House of Representatives Subcommittee on Health, Committee on Energy and Commerce, at a hearing on the "Discussion Draft of the 'Food and Drug Administration Globalization Act' Legislation: Device and Cosmetic Safety." The discussion draft that was the centerpiece of this hearing, if passed into law, would close some of the significant gaps in cosmetics safety discussed in these comments.

Next month FDA regulators will again attend the ICCR forum, in which cosmetic industry representatives and international regulators will discuss "removal of regulatory obstacles" and other issues related to cosmetic marketing and safety (FDA 2007a). Environmental Working Group (EWG) is writing to express deep concern that FDA officials are excluding public health, consumer, and environmental organizations from this meeting while allowing the regulated industry to participate. Such a process is inherently biased, conflicted, and unacceptable.

Last year EWG and the Campaign for Safe Cosmetics requested that the ICCR process be opened up to a broader group of stakeholders, including public health and public interest groups like the Campaign and the Environmental Working Group. Leaders in the U.S. Senate also wrote to FDA, noting major gaps in cosmetic safety and regulation and demanding that FDA "guarantee that interested stakeholders will be invited via public notice for all ICCR meetings" (Kerry and Boxer 2007). Despite the requests, once again FDA and the other ICCR representatives will meet in close-door sessions with the regulated industry, without broader representation from critical stakeholders.

Worse still, FDA's reasons for excluding other stakeholders last year were not based on fact (FDA 2007b). In a reply to the Campaign for Safe Cosmetics, the Agency noted "We discussed your request… with our ICCR regulator colleagues and internally at FDA. Everyone agrees that we should stick with our current Terms of Reference that provides for an industry association-regulator dialogue." Our detailed review of the Terms of Reference (ICCR 2007) finds no such restriction. In fact, we find just the opposite. The document supports involvement from other stakeholders, including, for example, in

language that details the meeting's "structured dialogue between members' representatives and industry trade associations, and in certain cases, interested parties." Given the growing evidence of major gaps in cosmetic safety our research has identified, this July's ICCR meeting is clearly a "certain case" in which EWG is one of many "interested parties."

While such an unbalanced discussion of consumer safety issues as the ICCR provides is always unacceptable, this exclusion is even more problematic in light of our analyses of product safety, which reveal that products sold in the U.S. frequently violate industry safety standards and contain ingredients banned in other countries. Our findings raise fundamental concerns about closed-door industry-regulator meetings that could further weaken international cosmetic policies.

We request once again that the ICCR be opened to a broader group of stakeholders. We believe this is critical to ensuring that the publics' interests are represented and that public health is fully protected in the decisions that are made.

Cosmetics, or personal care products, are essentially unregulated under the Federal Food, Drug, and Cosmetics Act (FFDCA). The Act includes 112 pages of standards for food and drugs, but just a single page for cosmetics (Tolchin 1990). This page provides the Food and Drug Administration (FDA) with virtually no power to perform even the most rudimentary functions needed to ensure the safety of an estimated $35 billion of personal care products purchased by consumers annually.

Under federal law and regulation, FDA (FDA 1995, 2005):

- Cannot require companies to test cosmetic products for safety before marketing.
- Does not review or approve cosmetic products and cosmetic ingredients before they are sold to the public.
- Cannot regulate cosmetic products until after they are released to the marketplace, and even then the process is extremely cumbersome.
- Cannot require product recalls. The agency must to go to court to remove misbranded and adulterated products from the market.
- Cannot require manufacturers to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries. Instead, FDA relies on voluntary reporting of ingredients, injuries and establishments.

In the absence of government authority, the safety of personal care product ingredients is evaluated through a voluntary industry program known as the Cosmetic Industry Review (CIR) process. In the words of John Bailey, former head of the FDA's Office of Cosmetics and Color and now head of the personal care products lobby group's science division, "In the absence of the CIR program, there would be no systematic examination of the safety of individual cosmetic ingredients" (FDA 1992).

This complete absence of accountability to a responsible government agency has not served the American public well. Instead, it has created a culture of ignorance around personal care products, where far too little is known about ingredient safety, while the industry and the FDA steadfastly maintain that all products and their ingredients are safe.

The Discussion Draft of the Food and Drug Administration Globalization Act would take vital steps to close these gaps by requiring cosmetic facilities to comply with some of the same requirements as other facilities: registration with the US Food and Drug Administration (FDA), requiring cosmetic manufacturers to report all anticipated and unanticipated serious adverse effects to FDA, and requiring good manufacturing practices. These actions are needed to close serious gaps in information on personal care products. But the draft is not yet law.

My testimony will focus largely on what we do and do not know about cosmetics. Unfortunately, what is not known about cosmetic ingredient safety is much greater than what is known. But, available data on serious safety gaps support action: we know enough to urge policy makers and public health officials to step up efforts to strengthen cosmetic safety standards.

The vast majority of ingredients have not been assessed for safety by the CIR, the FDA, or any other publicly accountable body.

The regulation of cosmetics is woefully outdated. The basic law regulating cosmetics has not been significantly updated for many decades. For the last 32 years, voluntary programs like the CIR, which companies are free to follow or ignore, have been used to deflect calls for reform and fend off the much-needed expansion of FDA authority to include review of ingredient safety. 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). At this pace, it will require another two and a half centuries to review the safety of all the ingredients in use by the cosmetics industry, assuming nothing new is introduced. And if CIR speeds up the process, the ingredient reviews could become so cursory and incomplete as to be nearly useless.

Companies are free to use almost any ingredient they choose in personal care products, with no proof of safety required.

FDA has prohibited or restricted by regulation only 9 ingredients in personal care products (FDA 2000a). The CIR has recommended restrictions on some uses of some additional ingredients, mostly to minimize skin irritation and allergic reactions, but has found only 9 ingredients unsafe for use in personal care products (a different 9 from FDA) (CIR 2006).

Companies are free to use any other ingredient they choose in cosmetics. Environmental Working Group's 2007 survey of products sold in the U.S. found nearly 400 products on the market that contain chemicals prohibited for use in cosmetics in other countries, and over 400 products containing ingredients that industry assessments have found unsafe when used as directed on product labels according to reviews by the CIR and the International Fragrance Association (EWG 2007a).

EWG's assessments of product ingredients reveal:

- A wide range of nano-materials may be common in personal care products (EWG 2007b). The safety of these ingredients is in question and is currently under study by multiple government public health agencies (NNI 2008).
- Phthalate plasticizers linked to birth defects of the male reproductive system and other health problems remain in common use in nail care products (EWG 2008a, EWG 2000, Houlihan et al. 2002).
- Companies still use hydroquinone in skin lighteners, despite FDA's proposed restrictions and warnings that the ingredient can lead to permanent skin disfigurement and may be linked to cancer and reproductive problems (FR 2006).
- Products contain a wide variety of ingredients derived from animal organs and tissues, including placenta expelled from cows (EWG 2008c), ingredients that raise concerns for the transmission of bovine spongiform encephalopathy (FDA 2007c), ingredients restricted in other countries (Health Canada 2007), and "ethically sourced" human placenta (Earthscience 2008).
- Studies show lead contamination in lipstick (CSC 2008) and cancer-causing impurities in

children's products and products labeled as "natural" (OCA 2008, EWG 2007c, Steinman 2007).

Since 2000, EWG has analyzed the safety of personal care product ingredients and the laws and regulations that govern them. We publish the results of this work as a part of our Skin Deep website, a searchable consumer tool that evaluates the safety of ingredients in 30,000 personal care products (EWG 2008b). An EWG analysis of product ingredients against definitive government, industry, and academic databases of hazardous chemicals finds that more than 1 in 5 of all products contain chemicals linked to cancer, 80% contain ingredients that commonly contain hazardous impurities, and 56% contain penetration enhancers that help deliver ingredients deeper into the skin.

Cosmetic ingredients penetrate the skin and may pose health risks, particularly for children.

Personal care products may be the primary exposure route for many chemicals that raise significant health concerns. Consumers can be exposed through skin absorption, inhalation, and ingestion. A personal care product use survey of more than 2,300 people, conducted by EWG and a coalition of public interest and environmental health organizations, shows that the average adult uses 9 personal care products each day, with 126 unique chemical ingredients. More than a quarter of all women and 1 of every 100 men use at least 15 products daily. The average woman uses 12 products containing 168 unique ingredients every day. Men, on the other hand, use 6 products daily with 85 unique ingredients, on average (EWG 2004).

Children are at particular risk from exposures to personal care product ingredients. Their skin is significantly thinner than an adult's, their ability to detoxify and excrete chemicals can be limited, and at birth the blood-brain barrier that can block chemicals' access to brain tissue is not complete (NRC 1993, EWG 2007d). In short, their developing bodies are more vulnerable to damage from hazardous chemicals.

Yet children's products are not assessed for their risks to children. In July and August of 2007, EWG surveyed more than 3,300 parents to find out what shampoos, lotions, bath soaps and other personal care products their children use. Based on the specific products named by these parents, we found that children are exposed to an average of 61 different chemical ingredients every day, and that on average 27 of these ingredients have not been found safe for children by the government or the cosmetic industry's expert safety panel (EWG 2007d, *see* attached Executive Summary).

Over the past decade, a steady stream of peer-reviewed scientific studies and reports from the Centers for Disease Control and Prevention (CDC) has documented the presence of chemicals from personal care products in the blood and tissues of most Americans, including young children. Many of these chemicals present serious health risks, and most have not been evaluated by the CIR or any authoritative body.

Scientists have found many common cosmetic ingredients in human tissues, including industrial plasticizers called phthalates in urine (CDC 2005), preservatives called parabens in breast tumor tissue and urine (Darbre et al. 2004, Ye et al. 2006), and persistent fragrance components like musk xylene in human fat, blood, and breast milk (Müller et al. 1996, Eisenhardt et al. 2001, Reiner et al. 2007).

Scientists at the Centers for Disease Control and Prevention (CDC) detected phthalates in urine samples from all but 12 of 2,790 people tested (CDC 2005), with six or more phthalates found in 84% of people tested. A recent study establishes a link between the use of shampoos and lotions on infants and the presence of a group of chemicals called phthalates in infants' bodies (as measured in urine). All babies in the study had at least one phthalate in them; 80% had seven or more (Sathyanarayana et al. 2008).

Over the past four years scientists have published at least 10 epidemiology studies linking phthalates to birth defects in baby boys, reproductive problems in men, abdominal obesity, increased diabetes risk, thyroid problems, as well as asthma and dermal diseases in children (Stahlhut et al. 2007, Meeker et al. 2007, Huang et al. 2007, Duty et al. 2003a, 2003b, 2004, and 2005, Hauser et al. 2007, Hauser et al. 2006, Wormuth et al. 2006, Marsee et al. 2006, Swan et al. 2005, Bornehag et al. 2004, Lottrup et al. 2006). This evidence joins many dozens of laboratory studies proving phthalates to be potent reproductive toxicants that target the male reproductive system, posing the greatest risks during development (Matsumoto et al. 2008, Gray et al. 2006, Frederiksen et al. 2007).

Some phthalates are banned from personal care product use in the EU; none are restricted in the U.S.

A 2008 study by the CDC found that 97% of Americans are contaminated with a widely used sunscreen ingredient called oxybenzone that has been linked to allergies, hormone disruption, and cell damage (Calafat et al. 2008b). A companion study published just one day earlier revealed that this chemical is linked to low birth weight in baby girls whose mothers are exposed during pregnancy (Wolff et al. 2008). Oxybenzone is also a penetration enhancer, a chemical that helps other chemicals penetrate the skin.

Triclosan, a common ingredient in anti-microbial soaps, was found in the urine of 61% of 90 girls age 6 to 8 by researchers from Mt. Sinai School of Medicine (Wolff et al. 2007). CDC found triclosan in 75% of the U.S. population in a recent study (Calafat et al. 2008a). Triclosan tends to bioaccumulate (Samsøe-Petersen 2003), or become more concentrated in the fatty tissues of humans and other animals. As a result, this chemical has been detected in human breast milk, and in blood samples as well (Adolfsson-Erici 2002; TNO 2005; Allmyr 2008. 2006a,b; Dayan 2007). Higher levels of triclosan in blood and breast milk are linked to use of body care products containing triclosan (Allmyr 2006a).

The overwhelming weight of the evidence indicates that chemicals in personal care products may be a serious health threat to the American public, and the FDA does not have the statutory authority or the resources to step in and protect the public.

Despite the potential risks, FDA does not even know how many ingredients are used in cosmetics.

The FDA does not have a basic understanding of the size and scope of the potential health risks from cosmetic ingredients, in no small part because the agency does not know how many ingredients are in cosmetics. And the cosmetic industry does not seem to know, either.

In 2000, FDA stated that, “It has been estimated that consumer expenditures for cosmetics exceed 35 billion dollars annually. It is further estimated that the marketed cosmetics are being produced in more than 1400 domestic manufacturing and repacking establishments and represent more than 25,000 product formulations. About 10,500 different cosmetic ingredients and a similar number of fragrance ingredients are being used by the cosmetic industry” (FDA 2000b). In 2007 FDA altered their estimate of ingredients to 12,500 (FDA 2007c).

Cosmetics industry officials, on the other hand, have variously estimated that the total number of ingredients used is "probably around 2,000" (Solomon 2004) or "really less than 4,000" (Bender 2005).

FDA sources show that the agency has records of 4,066 ingredients, as published in their ingredient dictionary and in the product database FDA has compiled through its Voluntary Cosmetic Registration Program (FDA 2008a, FDA 2008b). EWG has compiled ingredient listings for 29,037 products in our online product database (EWG 2008b), and as of May 12 2008 we find a total of 8,821 unique ingredients in our product database and FDA sources altogether, including 4,755 ingredients for which

FDA has no record.

Clearly, the industry's voluntary program for providing FDA with product ingredient listings is leaving FDA with grossly incomplete data on the full scope of ingredients used in products.

FDA does not know where and how many companies make and distribute personal care products.

FDA cannot require companies to register their cosmetics establishments with the agency, although they encourage companies to do so voluntarily. The absence of mandatory registration is a significant limiting factor in FDA's ability to ensure that cosmetics are not harming public health.

Without the ability to require pre-market safety testing, FDA must rely on facility inspections to assess product safety. A 1990 General Accounting Office study found that facility inspections are FDA's "primary enforcement tool for overseeing the cosmetics industry" (GAO 1990). Yet without mandatory registration, FDA does not know where and how many companies make and distribute personal care products. It is impossible for FDA to inspect facilities if their existence is not on record. And as the GAO noted, "Because FDA cannot mandate participation, it cannot accurately assess how many companies may be avoiding registration" (GAO 1990). FDA has estimated that marketed cosmetics are being produced in more than 1,400 domestic manufacturing and repacking establishments (FDA 2007c), but their registration system for these establishments is purely voluntary.

FDA does not know the extent of health impacts from harmful ingredients in cosmetics.

Twenty years ago the cosmetic industry staved off the threat of federal regulation with renewed pledges to increase the number of companies reporting adverse health effects from their products to FDA's voluntary reporting system. At the time, FDA reported that only 3% of distributors were filing injury reports. Though the industry claimed this was sufficient, since large companies with large market shares were participating, FDA noted that without injury data for each specific product on the market, they would be unable to identify all those that present safety problems (GAO 1990).

GAO found that voluntary injury reporting will fail: "FDA will never be able to require reporting from all companies, particularly those that may be least likely to report because they have experienced problems with their cosmetics" (GAO 1990).

In 2007 the cosmetic trade association launched a renewed effort to boost company participation in voluntary reporting, a program called the Consumer Commitment Code, again staving off renewed interest in stronger federal regulations. By signing the Code, a company agrees, among other things, to calculate "the incidence of adverse health effects in the United States (e.g., number per 100,000 or million units distributed) that have been medically confirmed as caused by the product in question" and to provide this information to FDA for inspection at a "mutually agreed location" when an FDA District Director submits a written request to the company's CEO or other designated official that is based on an explicit, legitimate, and specific safety concern with regard to the product (PPCP 2008).

This agreement might help mitigate the long-standing problem of companies refusing to disclose health information to FDA on their products (GAO 1990). But while better reporting of adverse events is a necessary first step to ensuring product safety, it alone will not give FDA the data it needs to understand the full range of health impacts from harmful cosmetic ingredients, even if the entire cosmetic industry participates and if FDA spends enormous resources sending staff to "mutually agreed locations" to inspect ingredient safety reports.

Consumers and their doctors might recognize skin irritation or allergic reactions as linked to particular products. But those cases will be the exceptions. Chronic health effects from chemicals in personal care products, like cancer, reproductive or nervous system effects are driven by genetic susceptibility, the timing of exposures, and aggregate exposures over a lifetime, and can almost never be traced back to individual consumer products. Exposures in the womb or early childhood, for instance, can lead to health problems much later in life (Lau et al. 2004). An injury reporting system that focuses only on acute, immediately observable adverse reactions will never help FDA understand other kinds of health risks. Only mandatory reporting systems, pre-market safety testing, and stronger safety standards for cosmetics will provide the information needed to ensure that personal care products are truly safe.

Consumers' right-to-know is hampered by lack of standards and labeling loopholes.

With no required safety testing for products, consumers must rely on labels for clues about a product's safety. Unfortunately, though, not all ingredients appear on labels, and not all claims printed on products must be backed by proof.

There is almost no regulation of marketing terms and other product claims. When FDA tried to establish definitions for the use of terms such as "natural" and "hypoallergenic," its regulations were overturned in court. Companies can use these and many other claims on cosmetic labels "to mean anything or nothing at all" (FDA 1998).

EWG's analysis (EWG 2007c) shows that 35% of all children's products marked as "natural" on the label are not completely natural, but instead contain one or more artificial preservatives linked to allergic reactions, hormone disruption, or nervous system problems in laboratory studies. Four out of five children's products marked as gentle and non-irritating (gentle, soothing, non-irritating, dermatologist approved, or free of harsh ingredients) instead contain ingredients linked to allergies and skin or eye irritation according to government and industry sources.

When the cosmetic trade association's chief scientist was head of FDA's color and cosmetic office, he noted: "Most cosmetics contain ingredients that are promoted with exaggerated claims of beauty or long-lasting effects to create an image… Image is what the cosmetic industry sells through its products, and it's up to the consumer to believe it or not" (FDA 1992).

Likewise, consumers' ability to make wise purchasing decisions is hampered by significant ingredient labeling loopholes. Federal law requires that all ingredients in a product appear in order of prevalence, but does not require that the ingredients in the "fragrance" added to a product appear on the label. Fragrances are usually complex mixtures of many chemicals. EWG's research shows that 44% of all products list the word "fragrance" on the ingredient label but fail to list what's in it (EWG 2008d). FDA has estimated that there are 12,500 ingredients in cosmetics, and an additional 12,500 chemicals used as fragrances (FDA 2007c), none of which are required to be listed on product labels.

Additionally, nanomaterials do not have to appear as such on product labels. Many ingredients are now produced in both conventional and nano-scale forms that may pose greater potential for exposure and health risks. Because there are no labeling requirements for nanomaterials, consumers have no way to know the difference.

Recommendations

The cosmetics industry has renewed efforts to boost participation in voluntary programs through its new Consumer Commitment Code. The ICCR process is yet another extension of a self-regulatory system

that has failed. The industry's 70-year track record in self-regulation shows that all of these efforts will fail to provide agencies with the information needed to protect public health. To fill the gaps, states are taking actions to restrict some of the most hazardous chemicals from products, independent certifications programs are increasing in number in attempts to provide meaningful standards for consumers, and groups and coalitions like the national Campaign for Safe Cosmetics are educating consumers on cosmetic safety and working directly with manufacturers to encourage the production of safer products. Until FDA can take enforceable actions when problems arise, the agency will remain unable to protect public health in the U.S. EWG recommends the following to ensure that personal care products are safe, particularly for those most vulnerable to the harmful effects of hazardous chemicals:

- **Mandatory registration of facilities.** FDA needs to know who is making personal care products, and what products they are making, as a basic first step to protecting the public health.
- **Mandatory, public injury reports (adverse event reporting).** FDA needs to know exactly which products may be endangering public health so that they can take the appropriate actions.
- **Registration of products and ingredients must be mandatory.** FDA must know what is in products if it is to protect the public from ingredients that may pose health risks.
- **Meaningful and proven labeling.** Product claims and marketing terms must be backed up by tests and must meet explicit definitions set by FDA.
- **Safety standards for cosmetics and FDA enforcement authority.** FDA's safety standard for cosmetics and its authority over cosmetic safety must be brought up to par with the agency's authority over pesticides and food and color additives under the Federal Food, Drug, & Cosmetic Act (FFDCA). FDA must have the mandate to ensure that ingredients are safe and the authority to demand the studies that it needs to make this finding. Cosmetic ingredients have been found in cord blood and they pollute the bodies of nearly everyone in the population; they should be as safe as pesticides, and food and color additives that meet safety standards under FFDCA.
- **Lastly, the ICCR meetings must be open to the public** to ensure that a broad range of stakeholders are included, so that the interests of more than just the regulated industry are represented.

Thank you.

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