

Should You Trust Your Makeup?

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FOR decades, companies that make everything from after-shave to lip gloss have conducted safety testing on grooming products and shipped the cosmetics to stores to be sold to consumers, all with very little government involvement. And over the years, there have been few health or safety problems associated with the myriad grooming products and cosmetics on the market.

Nonetheless, momentum has been building for greater oversight of the chemicals in everyday products, with the [European Union](#) and California taking the lead in imposing new rules for monitoring what is in the perfumes, creams, nail polish and hair sprays that are sold.

The California Safe Cosmetics Act, which took effect on Jan. 1, requires cosmetics companies to tell state health authorities if a product contains any chemical on several government lists covering possible cancer-causing agents or substances that may harm the reproductive system.

State Senator Carole Migden, Democrat of San Francisco, said that such chemicals, even in trace amounts, should be removed from beauty products because they have been found to cause cancer or hormonal changes in lab animals.

“The bill mandates that manufacturers reveal potentially poisonous ingredients,” said Senator Migden, the bill’s author. “I hope that the bill will lead manufacturers to voluntarily eliminate suspect ingredients from cosmetics.”

The cosmetics industry is already taking steps to heighten self-monitoring, though representatives said the ingredients that the California law regulates pose no risk to human health when used topically in the small quantities found in some cosmetics.

Indeed, no rigorous large-scale clinical trials have been conducted that would indicate that cosmetics trigger major diseases in humans. But some small case reports published in medical journals suggest that a few substances used in cosmetics may affect hormone function in humans.

Scientists are particularly interested in a group of chemicals called phthalates — used in some nail polishes, fragrances, medical devices and shower curtains — some of which have had an effect on the reproductive systems of lab animals and can be absorbed and excreted by the human body.

Although the cosmetics industry considers the phthalates used in its products to be safe, some companies have voluntarily removed dibutyl phthalate, which California considers harmful to the reproductive system, from their nail polishes.

But some environmentalists are pressing for a deeper analysis of the possible long-term effects of exposure to these chemicals. Some have formed a group called the Campaign for Safe Cosmetics to publicize their concerns, using the Internet to highlight ingredients and manufacturers. Their efforts have raised the possibility that the cosmetics industry eventually could be subject to greater government regulation, with perhaps mandatory testing and product approval.

Diana Zuckerman, president of the National Research Center for Women and Families in Washington, said that activists are singling out cosmetics because, unlike medical devices, they are optional purchases.

“If you are looking for chemical exposures that everyone can relate to, it’s not medical devices like IV bags,” Dr. Zuckerman said. “It’s shampoos and creams that are ubiquitous, that men, women and children are using every day.”

Since 1938, when Congress gave the [Food and Drug Administration](#) limited authority over beauty products, cosmetics has been a largely self-regulating industry. Prescription and over-the-counter drugs must submit safety data to the agency before it approves them for sale to the public. But cosmetics do not need agency approval because they are defined as topical products (like moisturizer or mascara) that alter neither the structure nor the function of the skin.

Beauty manufacturers are required to ensure the safety of their cosmetics before they go

on sale, but the federal agency has never defined safety, according to an agency spokeswoman. That has left it to the beauty industry to settle on a definition, with the overall standard being that products are safe for use if they do not irritate the skin when applied as directed.

By that standard, the industry has a long record of safety, with about six billion products manufactured annually worldwide, and only rare reports of problems like allergic reactions. Americans spent about \$50 billion last year on cosmetics and toiletries, according to Euromonitor International, a market research firm.

But some health groups have raised questions about the possible long-term or cumulative effects of exposure to all the chemicals in everyday products. In response to their concerns, the European Union imposed new regulations on the industry in 2004, banning more than 600 chemicals from use in cosmetics. In 2005, it went further to require more package information on product shelf life and allergenic ingredients.

Later this year, the European Union will take its oversight another step, instituting a policy called the Registration, Evaluation and Authorization of Chemicals (REACH), which will require companies — including cosmetics firms — that produce chemicals or use them in their products, packaging or manufacturing, to collect comprehensive data on the possible risks of the substances to human health and to the environment. The [European Commission](#) has estimated that the new law will cost the chemical industry as much as \$6.7 billion over the next decade, but that it could save up to \$70 billion in health costs over the next 30 years.

Part of the push for greater oversight stems from concerns about health trends, like increased reports of early puberty, asthma and allergies. Some scientists and health groups want to know if there is any connection to the aggregate exposure to chemicals.

A handful of small case studies and anecdotal reports, published in medical journals, suggest that a few ingredients used in some cosmetics could potentially have a hormonal or allergenic affect on humans.

A report published Feb. 1 in the [New England Journal of Medicine](#) described the cases of three preteenage boys who each used shampoo, hair gel or body products that contained either lavender oil or tea tree oil and who each grew breast tissue; the tissue receded after the boys stopped using the products. The researchers said their findings, though far from

conclusive, suggest that repeated exposure to these oils has the potential to affect hormones.

On Feb. 2, BMJ (formerly known as the British Medical Journal) published an editorial from doctors in which they cited reports of a marked increase in allergic reactions to hair dyes. The editorial called for increased scrutiny of hair dyes.

California has done the most of any state to address the issue of chemicals in cosmetics. Legislators in a few other states have discussed similar measures.

The cosmetics industry has not been resistant to greater disclosure. It has embraced the new European regulations, and it is working with California regulators to institute the new law.

But industry representatives said their goal is increased self-regulation, not government oversight. Toward that aim, the Cosmetic, Toiletry and Fragrance Association, an industry trade group, last month began to offer companies a voluntary program to make their safety data available to the F.D.A. and to report adverse reactions to the agency. They also said manufacturers would be more accountable to the guidance of an industry panel that reviews the safety of cosmetic ingredients.

At the same time, though, the industry has employed lobbyists to counter legislation and has argued that the new regulations are prompted by unsubstantiated fears rather than by hard science.

John Bailey, executive vice president for science of the cosmetics industry trade group, said that each beauty company conducts its own safety assessment of ingredients and final products. This typically includes a review of scientific literature to ensure that chemicals used in formulas don't cause toxic reactions or cell mutations in the body; patch tests on volunteers to make sure finished products won't irritate; and bacterial tests to make sure products won't spoil, he said.

Dr. Bailey added that substances being singled out by regulators and environmental groups are present in such small amounts in such a limited number of cosmetics that they pose no threat to human health. He compared them to salt in cooking.

“A little salt on your peas or tomatoes can be good,” Dr. Bailey said. “But a lot of salt can have adverse health effects on your blood pressure, and too much can be fatal.”

But some say the possible cumulative effect is exactly the point.

“They test in the short term for immediate reactions to make sure the product doesn’t cause your skin to itch, get red or fall off,” said Jeanne Rizzo, executive director of the Breast Cancer Fund, a nonprofit group in San Francisco that was one of the sponsors of the new California law. “But we don’t know the long-term effect of multiple exposures to chemicals in cosmetics that can get absorbed in your skin and end up in your urine or your bloodstream.”

Antonia M. Calafat, lead researcher at the National Center for Environmental Health at the [Centers for Disease Control and Prevention](#) in Atlanta, said the body’s absorption and excretion of chemicals do not necessarily indicate an impact on human health.

“All we can say at the moment is that humans are exposed to these chemicals, but the presence of a chemical in the body does not necessarily constitute a negative effect,” said Dr. Calafat, who added, “There need to be comprehensive, well-designed studies to understand whether indeed these compounds are harmful for humans.”

The chemicals that must be reported to health officials under the California law include lead acetate, found in some hair dyes; formaldehyde, which can be used as a cosmetic preservative; and toluene, a solvent used in some nail products.

“The law only requires that a cosmetic manufacturer with a product that contains a toxicant report it,” said Kevin Reilly, deputy director of prevention services of the state’s public health program. “But it will be interesting to see whether this bill drives reformulation of products.”