



US and European Union Approaches to Cosmetic Safety

UNITED STATES - The FDA

Contrary to popular belief, the Food and Drug Administration (FDA) does not regulate cosmetics in a manner comparable to drugs. In the FDA's own words:

No pre-market review: "The FDA is only able to regulate cosmetics after products are released to the marketplace. Neither cosmetic products nor cosmetic ingredients are reviewed or approved by the FDA before they are sold to the public."

No product registration: "FDA does not have the authority to require manufacturers to register their cosmetic products, file data on ingredients, or report cosmetic-related injuries. To keep abreast of such information, FDA maintains a *voluntary* data collection program."

No authority to recall: "Recalls are *voluntary* actions taken by the cosmetic industry to call back products that present a hazard or that are somehow defective. *FDA is not permitted to require recalls of cosmetics* but does monitor companies that conduct a product recall." (emphasis added)"

In other words, the FDA does not review what goes into cosmetics before they are marketed, cannot compel companies to provide data – including health effects data – and cannot recall products.

FDA Requirements for Cosmetic Labels Not Protective

Cosmetic labeling is regulated by a 1973 rule issued under the Fair Packaging and Labeling Act. The rule requires that a cosmetic label: "bear a declaration of each ingredient in descending order of prominence, excepting that fragrance, flavoring, and coloring may be declared as such." Unfortunately, numerous compounds can go into the fragrance, flavoring, and coloring and they are covered by this exemption. Reproductive toxins known as phthalates appear on the labels for nail polish – where they are used for flexibility – but not on the labels for various hair and skin products where the industry considers them a component of fragrance.

Manufacturers can also apply to have their ingredient considered a "trade secret" and therefore be exempt from disclosure. The phrase "and other ingredients" on the label indicates that the product contains an exempted chemical. FDA does not conduct a health-effects evaluation as part of its determination of a trade secret.

Cosmetics Ingredient Review: No Ado about Something

The Cosmetics, Fragrance, and *Toiletries Association* formed the Cosmetics Ingredient Review, a panel of scientists funded by the industry to address concerns about health effects of cosmetic ingredients. Unlike in Europe, where an independent government panel of experts prohibited

phthalates from cosmetics and adopted a broader policy of keeping carcinogens, mutagens, and reproductive toxins out of products, the cosmetics industry's CIR panel has concluded these actions are not necessary. And even if the FDA wanted to act, they lack the authority to do so.

EUROPE - The EU Cosmetics Directive

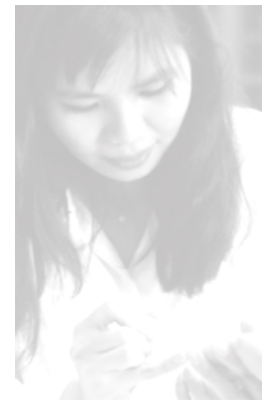
In January 2003, the European Parliament prohibited the use of certain chemicals that cause cancer, reproductive harm, or mutagenicity in cosmetics. The ban is absolute for chemicals that fall in categories 1 and 2 of these substances. For category 3, it is conditional– a manufacturer may use the chemicals only if the proposed use is determined to be safe. The policy took effect in September of 2004.

The categories denote the level of certainty that the chemical harms human health. Category 1 substances are those that are known to cause the specified health problems in humans. Category 2 substances are known to cause the effects in animals and the scientific literature is strong enough that the European Union (EU) has determined to treat the chemicals as though they cause the effects in humans. Category 3 substances have also shown health effects in animals, but the scientific literature is less robust than for category 2. These terms correspond to the terms "known," "probable," and "possible" used by the USEPA to describe health effects of chemicals.

The European Scientific Process

The list of carcinogenic, mutagenic, and reproductive toxicant chemicals (CMRs) was not created to deal specifically with cosmetics. It is a subset of a larger list of "dangerous substances," used by the EU for a variety of purposes. It is similar in that sense to various EPA and CalEPA lists of chemicals that meet certain scientific criteria. **Chemicals are added to the list based only on the available scientific data of their toxicity.** What to do about them is a separate matter of regulatory policy.

The policy decision of the EU was made as an amendment to its cosmetics law. The EU parliament was concerned to find that the most dangerous chemicals identified by scientists over the years were showing up in cosmetics, a category of products – unlike pesticides – to which consumers deliberately expose themselves. The parliament judged that the most dangerous chemicals should be prohibited from these products and others used only if



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they can be shown to be used safely.

The EU cosmetics law is not under legal threat in any European or international body, and cosmetics manufacturers have stated their intention to comply with it. As a result, consumers in Europe will enjoy the benefit of safer cosmetics. Unfortunately, not all cosmetic manufacturers have pledged to sell the improved formulations in the U.S. market and the FDA has declined to require them to do so.