

Federal oversight over cosmetic manufacturers:
the need for policy reform to advance worker
health and safety



VVE

Women's Voices for the Earth

deficiencies in the current regulatory system

- One of the least regulated consumer products on the market
- No restrictions on the use of harmful ingredients
- No requirements for pre-market safety assessments

Need for reform is long overdue

Federal Food, Drug and Cosmetic Act

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[Cross-reference of FD&C Act and U.S. Code section numbers](#)

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

SEC. 601. [21 U.S.C. 361] A cosmetic shall be deemed to be adulterated— 1

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a).

MISBRANDED COSMETICS

SEC. 602. [21 U.S.C. 362] A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this

paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

REGULATIONS MAKING EXEMPTIONS

SEC. 603. [21 U.S.C. 363] The Secretary shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

Footnotes: Chapter VI

¹ See [footnote for section 403\(h\)\(3\)](#) regarding the stylistic use of a list consisting of "(a)", "(b)", etc.

Problems with cir review

- Industry funded and self-policing
- Over a 30-year span, has only reviewed 11% of the 12,500 ingredients used in cosmetics
- Review process does not consider cumulative effects of exposure to toxic ingredients over a lifetime
- Does not take into account total exposure of cosmetic ingredients in combination with other chemical exposures
- Does not consider timing of exposure

Inadequate safety information

- Hazard Communication Standard requires manufacturers to provide MSDS to employees and customers
- Employers required to explain MSDSs to employees and alert them to potential hazards
- Shortage of OSHA inspectors to enforce the Standard
- Differences in Board licensing requirements makes it difficult to evaluate worker protections

U.S. Policy versus the EU

- EU Cosmetic Directive uses a hazard-based, precautionary approach
- Directive automatically bans chemicals that are known or highly suspected to be carcinogens, mutagens, or reproductive toxicants
- Bans hazardous ingredients regardless of levels in products

Voluntary measures

- Some manufacturers are voluntarily removing ingredients of concern
- No guarantee that substitute ingredients are any safer

SURVEY RESULTS

Confirmed nail polish is "three free"	Confirmed nail polish is not yet "three free"	Did not respond to letter
Acquarella	Creative Nail Design ¹	American Manicure
Butter London	Essie ²	Sally Hansen ³
Chanel		Sation
China Glaze		Yves Saint Laurent
CHI		
Colorpops		
Lippman Collection		
L'oreal USA		
NailTini		
OPI Products		
Orly International		
Rescue Beauty Lounge		
Revlon		
Seche		
SpaRitual		
Suncoat		
Zoya		

Footnotes

¹ Creative Nail Design nail polish currently contains toluene. In their response letter, Creative Nail Design clarified that their nail polish no longer contains dibutyl phthalate (as of 2004), has never contained formaldehyde and that several new toluene-free formulations were "in development."

² Essie products may still contain toluene and formaldehyde. In their response letter, Essie clarified that their

products comply with the European Union regulations (which ban dibutyl phthalate) and that they are "responding to our customer's concerns and are reformulating our nail products portfolio."

³ Although Sally Hansen did not respond to the Alliance regarding their use of the "toxic trio," the company's website states that their nail polish is now "three free."

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Recommendations for a new cosmetic policy

- Pre-market safety assessment of all cosmetic ingredients
- Ban on chemicals linked to cancer, mutation, and reproductive harm
- Full ingredient listing on product labels and company web sites, including the constituent ingredients of fragrance and salon products
- FDA requirements for substantiating the safety of ingredients used to formulate cosmetics
- A grants program to encourage the creation of innovative solutions and safe alternatives to toxic chemicals in cosmetics
- Right-to-know information about hazardous chemicals in cosmetic products and manufacturing practices for workers
- Adequate funding to ensure the FDA Office of Cosmetics and Colors has the resources it needs to provide effective and meaningful oversight
- Timetable for safety testing ingredients already used in cosmetics, prioritizing those chemicals with known or suspected adverse health impacts

Short-term recommendations

- Voluntary removal of chemicals of concern
- Easy to understand, multi-lingual safety information
- Better labeling and warnings
- Incorporate safety information regarding toxic exposure into licensing exams
- Improve ventilation in salons
- Ensure greater access to health care and occupational medicine
- Ensure the needs of nail salon and cosmetology service community are included in the state's green chemistry initiative

For More Information:

GLOSSED OVER



Health Hazards Associated with
Toxic Exposure in Nail Salons



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