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# Cosmetics Regulation in the United States and the European Union: Different Pathways to the Same Result

*By Richard Kingham and Lucas E. Beirne*

## Introduction

It is sometimes suggested that cosmetic products are more strictly regulated in the European Union (EU) than in the United States and that the EU system is, for this reason, a better model than its U.S. counterpart. In fact, however, the approach to regulating cosmetics in the EU and the United States is fundamentally the same.

In contrast to many developing countries, neither the EU nor the United States imposes a requirement for government

licensing or premarket approval of cosmetic products. Instead, both jurisdictions rely on manufacturers to substantiate the safety of their products according to principles established by regulations. Nevertheless, both systems require prior review and approval of a limited number of specific types of cosmetic ingredients, such as color additives and sunscreens. Both also authorize regulatory authorities to ban or restrict the use of certain ingredients, to require warnings on product labels, and to take other precautionary measures. Independent expert



**Mr. Kingham** is a partner in the Washington, DC, and London offices of Covington & Burling LLP.

**Mr. Beirne** is a student at the University of Virginia School of Law. He was a summer associate at Covington & Burling LLP in 2011.

bodies have been established in both the EU and the United States to review test data on ingredients and render opinions on their safety for use in cosmetics. Both jurisdictions require manufacturers to substantiate promotional claims for cosmetics, and both establish systems for inspection and enforcement. Although the precise manner in which these powers are exercised differs between the two jurisdictions—due in part to historical factors—the end result in both cases is essentially similar, and both systems assure high standards of quality and safety.

### The U.S. System: Statutory Framework

The U.S. regulatory system for cosmetics was established in 1938, nearly 40 years before its EU counterpart, and has evolved since then to meet changing requirements. The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA)<sup>1</sup> granted broad authority to the Food and Drug Administration (FDA) to ensure that cosmetics are safe and truthfully labeled. The statute prohibits the use in cosmetics of poisonous or deleterious substances that may render them injurious to users under customary conditions of use; manufacturing or holding cosmetics under insanitary conditions; and use of labeling that contains false or misleading statements, fails to reveal material information, or omits required information.<sup>2</sup> The statute grants FDA authority to issue regulations; inspect manufacturers and sellers of cosmetics; and initiate enforcement actions, including seizure of violative goods, injunction actions, and criminal prosecutions of companies and responsible individuals.<sup>3</sup>

Although the FDCA does not establish any requirement for premarket approval of cosmetic products, it contains broad provisions governing drugs that—unlike their EU counterparts—do not preclude

dual classifications. Thus, cosmetic products for which claims are made for the prevention or treatment of disease or for affecting a structure or function of the body can be regulated as both drugs and cosmetics.

The FDCA was accompanied by the Wheeler-Lea Amendments<sup>4</sup> to the Federal Trade Commission (FTC) Act, which granted additional powers to FTC to regulate advertising of cosmetics and other products subject to the FDCA. The FDCA also left intact systems of regulatory control at the state level, including general food and drug laws, administrative rulemaking powers, and provisions for state and local inspections and enforcement actions.

### Color Additives and Drug/Cosmetic Products

The statutory framework established in 1938 has been greatly augmented over time. Amendments to the FDCA enacted in 1960 established a requirement for premarket approval of color additives used in foods, drugs, and cosmetics.<sup>5</sup> FDA regulations list permitted colorants and required conditions of use.<sup>6</sup>

FDA has used its authority under the FDCA to impose drug controls on a number of major categories of cosmetic products. Examples include antiperspirants, anticavity toothpastes, antimicrobial mouthwashes, antimicrobial handwashes and hand sanitizers, antidandruff shampoos, and sunscreens. Although these products are not subject to premarket approval, they are governed by monographs issued under FDA's Over-the-Counter (OTC) Drug Review that establish permissible active ingredients and key aspects of labeling, such as precautionary statements and instructions for use.<sup>7</sup> These products must also comply with other requirements for OTC drugs, including adverse event

reporting<sup>8</sup> and current good manufacturing practices.<sup>9</sup>

Acting in cooperation with the cosmetics industry, FDA has established a comprehensive regime to provide the public with information concerning cosmetic product formulations and ensure the safety of cosmetics. The agency has imposed requirements for ingredient declarations in the labeling for cosmetics, relying on authority under the Fair Packaging and Labeling Act.<sup>10</sup> Those regulations incorporate terminology contained in an industry-sponsored ingredient dictionary that has formed the basis for international cosmetic ingredient nomenclature adopted in the EU and other jurisdictions around the world.<sup>11</sup>

### Safety Substantiation

An FDA regulation requires manufacturers to substantiate the safety of their products or label them with a warning that safety has not been established.<sup>12</sup> A panel of experts convened under the Cosmetic Ingredient Review, an industry-funded but independent organization in which FDA participates, reviews data on the safety of cosmetic ingredients and issues reports that can be used as the basis for compliance with FDA's safety substantiation requirement.<sup>13</sup>

FDA has also established voluntary systems for registration of cosmetic establishments and listing of product formulations,<sup>14</sup> and the agency receives voluntary safety reports from cosmetic manufacturers.<sup>15</sup> Finally, FDA has issued a number of regulations and policy statements banning or restricting the use of specific ingredients in cosmetics and establishing requirements for safe use.<sup>16</sup>

### Enforcement Resources

All of these measures are backed up by the resources of the largest consumer protection agency in the world. FDA now

has a staff of more than 11,000 persons,<sup>17</sup> about half of whom serve in district and field offices around the United States and inspection posts abroad. FDA's resources are supplemented by those of FTC and state governments, as well as nongovernmental organizations such as the National Advertising Division of the Council of Better Business Bureaus and the broadcast networks.

## The EU System

The present system of cosmetics regulation in the EU has its origins in a directive issued in 1976 by the Council of Ministers of what was then known as the European Economic Community (EEC).<sup>18</sup> The main purpose of the directive was to harmonize national regulations in order to reduce obstacles to free movement of products across national boundaries. Consumer protection was an important, but secondary, goal.

The original directive contained relatively modest provisions, including requirements for labeling, without ingredient declarations; a general requirement that products be safe, without detailed requirements for substantiation of safety; lists of permitted and provisionally listed coloring agents; and lists of banned and restricted substances. The initial list of banned substances, which included 361 entries, was derived from pre-existing national lists in certain member states (especially France), and contained many ingredients that had, in fact, never been considered for use in cosmetics (e.g., barbiturates and narcotics), but were instead used in prescription medicines. Provisions were included for amendments to the ingredient lists via secondary legislation issued by the European Commission and a standing committee of member state governments based on recommendations from a committee of scientific experts.

There was no requirement for premarket approval of cosmetic products. The European Parliament suggested such a requirement, but it was rejected by the Commission and the Council.<sup>19</sup> The report of the EEC's Economic and Social Committee explained that the system chosen "means that any substances not explicitly forbidden by the Directive are permitted, provided that these raw materials or their combined use can in no circumstances be harmful to human health. In any case, the manufacturer ... remains responsible."<sup>20</sup>

Subsequent amendments to the directive added positive lists for permitted preservatives and UV filters (i.e., sunscreens), established a requirement for ingredient declarations, adopted a ban on animal testing, created more detailed requirements for safety substantiation (including a requirement for a safety dossier on each marketed product), and otherwise rounded out the regulatory regime.<sup>21</sup>

There was no provision for direct regulation of cosmetic products by any entity at the European level. Instead, each member state was required to transpose the provisions of the directive into national law. All enforcement, including inspections and legal actions to secure compliance, was entrusted to the member states. Product promotion, including claims substantiation, was also regulated under general EU measures governing misleading advertising,<sup>22</sup> and there was great disparity among the member states as to resources and mechanisms for enforcement.

## New Cosmetics Regulation

Most recently, the EU has adopted a cosmetics regulation that will eventually supersede the directive and apply directly in the member states.<sup>23</sup> There will be requirements for premarket

notifications through a centralized system (but not premarket approval) for finished products containing nanomaterials, postmarketing surveillance with reporting of serious undesirable effects to government authorities, and other enhanced regulatory responsibilities. But the basic framework will remain the same, and enforcement will continue to be the responsibility of the member states, without any EU-level cosmetics agency or enforcement authority.

## Conclusion

The United States and the European Union have thus reached more or less the same point by different routes, and the systems they have established are remarkably similar. Key elements of the systems in both jurisdictions include:

- Flexible provisions for introduction of new products that rely on manufacturers to substantiate safety and proof of claims according to principles set out in regulations, rather than a system of government licensing or premarket review.
- Expert committees to advise on the safety of ingredients used in cosmetics.
- Requirements for informative labeling, including ingredient declarations and, where necessary, instructions for use.
- Positive lists of certain types of ingredients (e.g., sunscreens and color additives), supplemented by regulatory authority to ban or restrict the use of other ingredients as necessary to protect consumers.
- Postmarketing controls, including provisions for inspections and enforcement actions to ensure compliance with requirements for labeling, product safety, and substantiation of claims.

The result, on both sides of the Atlantic, has been a high level of product safety and quality, which has been achieved without imposing unnecessary regulatory obstacles to the introduction of new products for consumers. Cosmetics remain among the safest products in both the United States and the European Union, and there are very few products that cannot be marketed in essentially the same form in both jurisdictions. ▲

1. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938), 21 U.S.C. §§ 301 et seq.
2. 21 U.S.C. §§ 321(n), 361, 362.
3. 21 U.S.C. §§ 332, 333, 304, 374.
4. Wheeler Lea Act of 1938, ch. 49, 52 Stat. 111 (1938).
5. See 21 U.S.C. § 379e.
6. 21 C.F.R. Parts 70-82.
7. 21 C.F.R. Part 330 et seq.
8. 21 U.S.C. § 379aa.
9. 21 U.S.C. § 351(a); 21 C.F.R. Parts 210-211.
10. See 21 C.F.R. Part 701.
11. For a description of the Cosmetic Ingredient Dictionary, see [www.cosmeticsinfo.org/fdapartner\\_cid.php](http://www.cosmeticsinfo.org/fdapartner_cid.php).
12. 21 C.F.R. § 740.10.
13. A description of the Cosmetic Ingredient Review can be found at [www.cir-safety.org](http://www.cir-safety.org).
14. 21 C.F.R. Parts 710, 720.
15. The system for adverse event reporting is described in the industry's Consumer Commitment Code at [www.cosmeticsinfo.org/fdapartner\\_ccc2.php#2](http://www.cosmeticsinfo.org/fdapartner_ccc2.php#2).
16. See 21 C.F.R. Parts 700, 740.
17. See [www.fda.gov/AboutFDA/Transparency/Basics/ucm213161.htm](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm213161.htm).
18. Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, 1976 O.J. (L 262) 169-200.
19. See, e.g., Resolution embodying the opinion of the European Parliament on the proposal, 1973 O.J. (C 62) 43-48.
20. Consultation of the Economic and Social Committee on a proposal for a Council Directive on the approximation of the laws of the Member States on cosmetics, 1973 O.J. (C 60) 17.
21. A consolidated version of the directive can be found at [http://eurlex.europa.eu/consumers/sectors/cosmetics/documents/directive/index\\_en.htm#h2-consolidated-version-of-cosmetics-directive-76/768/eec](http://eurlex.europa.eu/consumers/sectors/cosmetics/documents/directive/index_en.htm#h2-consolidated-version-of-cosmetics-directive-76/768/eec).
22. Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations, and administrative provisions of the Member States concerning misleading advertising, 1984 O.J. (L 250) 17-20, as amended. A consolidated version of the directive can be found at <http://eur.lex.eu/LexUriServ.do?uri=CELEX31983L0450:EN:NOT>.
23. Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, 2009 O.J. (L 342) 59-209.