11 Regulation of cosmetic products

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11.1 Historical development

The modern day mass market toiletry and cosmetic industry began in the US in the early years of the 20th century, and particularly between the two world wars. Whilst the industry record for in-use safety of its products was good, this rapid expansion in consumer exposure gave rise to calls for action to pre-empt possible problems that could arise. Consumer pressure and advances in the science of toxicology added to the general concern.

In the US, the Pure Food and Drugs Act of 1906 [1], enacted to extend formal federal controls over foods and drugs, did not include cosmetics, reportedly as the result of a political compromise [2]. Not until passage of the Food, Drug and Cosmetic Act in 1938 [3] were cosmetics included in the general prohibitions against manufacturing and marketing adulterated or misbranded products. The 1938 Act also made it possible for products previously unregulated to come under Food and Drug Administration (FDA) [4] control as drugs if they were intended not only for medicinal and therapeutic purposes, but also if they were intended to affect the structure or function of the body. The 1938 Act has since been amended to control the safety of cosmetic colors. Regulations under both the FDC Act and the Fair Packaging and Labeling Act (FDCA), administered by FDA, restricted or prohibited cosmetic ingredients found to be unsafe and required extensive informative labeling of cosmetic packaging.

Other national and regional governments have likewise sought to govern cosmetic products. In Japan, cosmetics are included in the Pharmaceutical Affairs Law administered by the Ministry of Health and Welfare. The law requires that cosmetic manufacturers and importers be licensed and that each cosmetic placed on the Japanese market either be in conformance with the monographs that make up the Comprehensive Licensing Standards of Cosmetics or have obtained direct individual approval from the Ministry.

In Europe prior to 1976 there was no comprehensive control of cosmetics and local legislation varied widely. Some countries, e.g. Germany, already had a highly developed regulatory system, whilst others relied almost solely on rather antiquated rules for poisons control. With the development of the then European Economic Community, later the European Community and now the European Union (EU), with its twin aims of free movement of goods
between member states (MS) and consumer safety, this situation was unacceptable. In 1976 the then MS agreed a Directive on Cosmetic Products which would be applicable to the Community as a whole. In the pursuit of adaptation to technical progress, this Directive has, in the meantime, been amended no less than 24 times.

Other countries have developed their own regulatory styles, but in the main these are based on those of one of the three major markets: Japan, USA or Europe.

11.2 Self-regulation

In many areas of the world, and especially in the US, the cosmetic industry has embarked on voluntary programs aimed at improving the safety and effectiveness of cosmetics and at the same time, at avoiding more intrusive government regulation. These activities have included codes of good practice and self-regulatory programs such as voluntary registration of cosmetic manufacturing establishments, cosmetic products and ingredients, and voluntary reporting of adverse reaction experiences. In addition, in the US, the industry has undertaken a program [the Cosmetic Ingredient Review (CIR)] to assess the safety of cosmetic ingredients through an independent panel of scientific experts which meets, deliberates and publishes its findings. CIR reports on specific cosmetic ingredients are used by industry and government to establish the safety of these materials. In addition, the perfumery industry set up the international organizations IFRA (International Fragrance Research Association) and RIFM (The Research Institute for Fragrance Materials) to examine and review perfumery materials, and to control their use. The aerosol industry published a code of practice for manufacture of aerosol products, while the European Chemical Industry set up ECETOC as a review body to control information on the safety of chemical substances. COLIPA (Comité de Liaison des Associations Européennes de l’Industrie de la Perfumerie des Produits Cosmetique et de Toilette), the representative body for trade associations within the EC, published ‘Advisory Notes to Manufacturers’ together with a number of other advisory documents covering the safety of cosmetic and toiletry products. These included the ‘Education and Training of Personnel’, ‘Product Safety Verification During Marketing’ and ‘Avoidance of Nitrosamine Formation in Cosmetic Products’.

Although much of the voluntary activity described eventually led to legislation, there still remains a wealth of voluntary activity, and the legislation imposed has been maintained at realistic levels. Industry continues to adjust its voluntary controls in the light of consumer pressures, environmental concerns and legislation in other areas that impinges on the products manufactured and sold as cosmetics and toiletries. Constant vigilance and awareness of these issues is imperative for all scientists aspiring to create new approaches and new products in this area.