

Cosmetics: Regulatory Scenario in USA, EU and India

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ABSTRACT The efficacy, safety, regulatory framework and marketing of cosmetic products are the most important factors for growth of cosmetic industry. The safety of the cosmetic goods are regulated by diverse regulatory bodies around the globe who all have their own rules and regulations. The regulations of cosmetics like, nomenclature, labelling and safety of colorants(s) alter in different countries. Much stringent legislation exists in European Union (EU) and The United States of America (USA) have very much stringent legislation in order to regulate the use of cosmetic products. The safety assessments of cosmetic products is affected by the different regulations of different regulatory bodies. Nevertheless, there is a need for harmonized regulations throughout the world. An attempt has been made in the present manuscript to compare the current regulatory scenario of cosmetics in USA, EU and India.

Keywords: Cosmetics, Safety Issues, Color Additives, Regulatory Guideline

1. INTRODUCTION

Cosmetics have been in use since ages for regenerating the appearance of the person laying on them. Beauty cosmetics can build an extreme change in a person's features, as they cover the blemishes and improve the best features (Groves and Mizerski, 2005). The word cosmetics derives from the Greek word (*kosmetikē tekhnē*), meaning "ornament and technique of dress", from (*kosmētikos*), "arranging or skilled in ordering" and that from (*Kosmos*), meaning amongst others "ornament" and "order". The first archeological evidence of cosmetics comes from the hollowed out tombs of the ancient

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Egyptian Pharaohs. Archaeological testimony of cosmetics dates atleast from ancient Greece and Egypt (Liddell and Scott, 2013). *Tremella fuciformis* fungus is one of the most popular traditional Chinese medicines; used as a beauty manufactured goods by women in China and Japan. The fungus apparently increases the moisture retention and also prohibits the senile degradation of micro-blood vessels in the skin, smoothing fine lines and reducing wrinkles. Other anti-ageing effects come from escalating the presence of superoxide dismutase in the liver and brain; it is an enzyme that acts as a effective antioxidant all over the body, specifically in the skin (Reshetnikov *et al.*, 2000).

Universally cosmetic industry sales have reached about \$170 Billion dollars a year. It's distributed pretty systematically around the world with ~\$40 billion in the Americas, ~\$60 billion in Europe, ~\$60 billion in Australia and Asia, and another \$10 billion in Africa (Romanowski, 2014). In India, cosmetics market is rising at 15-20% annually, twice as fast as the European Union (EU) and the United States America (USA) market. The Indian cosmetic industry is the beautiful blend of modern and traditional cosmetics. The cosmetics regulations put forward by the authorities assure the consumer by ensuring safe products and thus safe ingredients. In the world, United States of America and Europe have emerged as the biggest markets for cosmetic products. The decorative cosmetics have the topmost average annual growth rate as far as end user segments are concerned (CTFA-US Cosmetic, Toiletry and Fragrance Association, 2007). The product safety is ensured before marketing is done by the cosmetics manufacturers in the European Union (EU) and United States of America (USA). All the ingredients are mentioned along with the limits that are recognized for the cosmetic ingredients and products on the product label and the limits mentioned comply with the established limits. The regulatory analysis in the US is more abstract to color additives than in Europe. In the USA, the Cosmetic Ingredient Review (CIR) expert panel conducts the liberated safety scrutiny of the ingredients as a part of the cosmetic refugee process and publishes the results on the CIR website and in the International Journal of Toxicology. All special and active ingredients are reviewed by the EU scientific committee. This committee also determines the conditions for safe use of products for consumers (Srikanth *et al.*, 2011). In India, under the Drugs and Cosmetics Act, 1940 and Rules, 1945 and labeling declarations by Bureau of Indian Standards (BIS) the cosmetics products are regulated. Under Schedule 'S' of the Drugs and Cosmetics Rules, 1945, BIS sets the standards of cosmetics for the products listed. BIS has provided the specification for skin creams and lipsticks in the Indian Standards (IS) 9875: 1990 and 6608:2004, respectively. As per IS 6608:2004, if all the raw materials demanding heavy metals testing act in accordance with the requirements,

then the producer may not examine the ended cosmetic for heavy metals and arsenic (Regulation of cosmetics, <http://www.cseindia.org/node/5289>). There exists some dissimilarity in cosmetic regulations of different countries like USA, EU and India. The streamlining of regulatory framework in order to make it harmonized will definitely play an important role in the growth of the market at an international level, removal of barriers to trade, innovation in the development and most importantly safety of the marketed products. The goal of the present article is to highlight the regulatory scenario and to compare the regulations in USA, EU and India for cosmetic with respect to labeling, quality and safety of the products.

2. SAFETY ISSUES AND ASPECTS

The safety of cosmetic products is ensured primarily by the manufacturer. In summation, a set of regulatory elements is effective to bar the use of hazardous components in cosmetics. In the future, major changes in the safety assessment of cosmetic ingredients are expected considering the prohibition of animal experimentations. The present practice of ensuring high degree of consumer protection must be kept up; furthermore, innovations should be placed into practice without unacceptable risks to the consumer (Platzek *et al.*, 2010).

2.1 United States of America (USA)

Color additives may be used just for the predictable uses acknowledged in the regulations that relate to them. Other limitations are particular by the regulations for definite colors, such as the highest allowable concentration in the end product. Natural and inorganic colors are taken from this documentation. 64 color additives for cosmetic use without or with batch certification has been approved by FDA (21 CFR Part 73, 2007) one of which is mica. Except for lip products, aluminium colorants are permitted for all cosmetic applications. Ferric ferrocyanide may be used in the USA for the external applications. For colorants, A color additive labeling guide is approved in the U.S and FDA and color additive names (Drug and Cosmetics Orange No.10 and 11) are banned in the USA (Sujit and Roop, 2012).

2.2 European Union (EU)

The EC cosmetics directive (76/768/EEC) in the European Union covers the safety of cosmetics as amended. Annex IV to cosmetics directive 76/768/EEC provides for a “*for use in cosmetic products, list of coloring agents are permitted*”. The permissible use refers to dissimilar fields of applications. This is carried out in the UK by the decorative products (safety) regulations 2008.

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For example, Aluminium colorants are accepted for all decorative applications in EU whereas Mica is not considered as colorant in the EU. For external application in the lip area, ferric ferrocyanide may be used in the EU (EC Cosmetics Directive 76/768/E, 1998).

2.3 India

Inclusion of 158 coloring agents is mentioned in the IS 4707 (part 1): 2001 under clause 4.1. In the manufacture of lipstick and skin creams the dyes colors (pigments lakes) shall act in accordance with with IS 4707 (Part I) focus to the stipulation of Schedule Q of Drugs and Cosmetics Act and Rules, issued by the Government of India. Rules 134 of Drugs and Cosmetics Rules have laid down limitations on the usage of cosmetics containing pigments, dyestuffs and colors other than those prescribed by the schedule Q and BIS (IS: 4707 Part as amended) (Regulation of cosmetics, 2014). These are Generally Recognized As Safe (GRAS) compounds and their upper limit concentration is prescribed in the end product and they should also fulfill the purity requirements (Classification of cosmetics, 2005).

3. NOMENCLATURE OF COLOURS

The regulatory bodies and the manufacturers of cosmetic products have been discussing on the designation of the color additives on cosmetic product labels for many years. There should be a uniform and simpler system that could be used broad in a sense for identifying the color additives, so that, all the cosmetic products have uniform terms for similar ingredients (Regulation nomenclature in the United States, 2005).

3.1 United States of America

In USA, the official names of color additives for cosmetics are designated by the Food Drug and Administration (21 CFR Part 73). Colors are subject to batch certification and are pursued by a number (numeral), such as blue or red, and by a color naming. Food, Drug and Cosmetics red No. 40 is an object example of such a figure. The colors created by incorporating the “*substrates*” (aluminum, sodium, potassium, barium, zirconium, or calcium, strontium) with “*straight*” colors are recognized as “*lakes*” and are identified by the similar conference, by the inclusion of the word lake and the substrate, for example: Food Drug and Cosmetics red No. 40 Aluminium Lake. As in batch certification, cosmetics colors such as henna or caramel are known by their common names so, these must be pre-approved, prior to being used in cosmetic products in the USA. Food drug and administration also enforce marketing

companies to apply their goods worldwide by twofold labeling of colors, listing names acceptable to the FDA as well as Color Index (CI) numbers that are required for labeling clause in the European Union and other nations. So, for instance, a cosmetic product in the USA may have an ingredient labelling for colors such as Food, Drug and Cosmetics yellow No. 5/CI 19140 or yellow 5/CI 19140 (Colors in cosmetics, 2005). The products having the certifiable lakes or colors can be named in the abbreviated form on the labels by the cosmetic industry as per the permission given by FDA. For example, Food, Drug and cosmetics red No. 40 Aluminium Lake may now be listed as Red 40 Lake and, Food, Drug and Cosmetics Blue No. 1 now may be listed as Blue 1. The original color names may also be employed.

3.2 European Union

International nomenclatures of cosmetic ingredient (INCI) names are attested for the purpose of coloring agents. EEC directive mentions that coloring agents may be listed in any parliamentary procedure using the Color Index (CI) Number or faith adopted after the other constituents. European parliament selected European Commission (EC) to sort and fix the regulations on food additives and recognized common authorization procedure for food enzymes, food additives and food flavorings (EC No 1333/2008). As per this rule, it was required to have a reference standard (as formerly prepared for food additives as per Commission Directive 2008/128/EC of 22 December 2008) to be laid down for definite purity criteria relating to colors for use in food products. For example, Food colors brown FK and E154 (ethyl ester of beta-APO-8-carotenic acid (E160f)) and also the aluminium containing carrier bentonite (E558) are not to be used any further as per information to be complied by food manufacturers in European union. Therefore, the precondition of use the colors is also annexed to the rule. It incorporates the definition of that peculiar color, its brief manufacturing process in order to know the standard preliminary materials for the same and specifications to which it should comply (Kanekar and Khale, 2014).

3.3 India

In reference to Drug and Cosmetic Act, 1945 and rule thereunder, the 127 clause (2) of the drugs, the usual name of the permissible color should also be mentioned on the container of a drug, for example: Erythrosine, Tartrazine, Quinazarine Green SS, etc. But this is not applicable for cosmetics. No instruction is given in the Drug and Cosmetic Act and principles for the nomenclature of coloring agent. Color index 14700 mentioned on the label of Pond's White Beauty Cream

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(Hindustan Unilever Limited), Garnier Wrinkle Lift anti-ageing cream (Loreal India Pvt. Limited) does not give information about any color. Lactocalamine (Nicholas Piramal India Limited) contains “*permitted color*” on its label. New Ever Youth Orange Peel Off Skin Vitalizer (Cadila Healthcare Limited) does not mention any color. The color is mentioned as ultramarines on the label of artistry basics polishing scrub (Amway India Enterprises Pvt. Limited). Glister toothpaste (Sarvottam Care, India for Amway India Enterprises Pvt. Limited) mentions the color as Food, Drug and Cosmetics Blue No 1 (CI 42090). So, from these instances it is clear that in India, there is need for more synchronization in the nomenclature of colorants (Sujit and Roop, 2011).

4. REGULATORY GUIDELINE

4.1 United States of America (USA)

The cosmetics are defined as “*articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body’s structure or functions*” in the US. The most commonly known cosmetic products are fingernail polishes, lotions, skin creams, lipsticks, toothpastes, deodorants, perfumes, shampoos, eye and facial makeup preparations, hair colors and permanent waves. Soap goods consisting chiefly of an alkali salt of fatty acid and making no label state other than that the cleansing of the human body are not considered cosmetics under the law (U.S. **Food and Drug Administration, 2014**). As divergent to drugs, cosmetic products do not involve confirmable, compulsory fulfillment before they can be commercialized. In the United States, utilizing the Voluntary Cosmetic Registration Program (VCRP) is minimum expected from the manufacturers, packers and distributors of ornamental goods that are in profitable distribution. VCRP provides FDA with the finest data obtainable in relation to the cosmetic products and its factors, their fabrication and distribution and their frequency of exercise. The manufacturer, packer or distributor should file a report known as Cosmetic Product Ingredient Statements (CPIS) in the United States, for every product that the firm has introduced into the market (Deepthi and Sudheer, 2013). As per the law of administration, the FDA may perform investigations and examine the products and the establishments in which products are manufactured or held, misbranded (incorrectly or deceptively labeled or filled) or seize adulterated (harmful) cosmetics. Cosmetics and Personal Product Act of 2013 is planned to give the US FDA power to make sure those personal care products are fully exposed and without harmful constituents. The cosmetics regulation which concerns misbranded and adulterated cosmetics is amended in the Federal Food, Drug, and Cosmetic Act in such a manner that it requires

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1. Once a year registration of any enterprise occupied in promotional material, fabrication, or distributing cosmetics
 2. Expense of amount to give for oversight and fulfilling of regulations of cosmetics,
 3. Need revelation of information and labeling of ingredients and
 4. Reporting of adverse event.

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The Act calls for the secretary to set up a record of banned ingredients and a record of components that are safe and sound without limits for purpose of use in cosmetics and determine the minimum data necessities and test protocols to be practiced by producers to estimate the safety of the cosmetic components. The Act also sets forward requirements related to nanotechnology in the manufacturing of cosmetics, mandatory and voluntary recall of cosmetics and alternatives to testing of animal. The Act constitutes the “*Interagency Council on Cosmetic Safety*” to share the data and as well as the support association on cosmetic safety with federal authorities. A cosmetic that fails to convince the labeling requirements under this human activity is held to be misbranded (Federal Food, Drug, and Cosmetic Act, 2013). The Fair Packaging and labeling Act is to guarantee that package and their labels should offer consumers with precise data to facilitate value comparisons and contents quantity details (15 U.S. 1451-1460). This includes inserts, labels, display packs, risers, promotional literature, booklets or any other printed or written information disseminated with manufactured goods (Cosmetic Labeling Guide, 2015) under the law the label statements must emerge on any outside container or wrap and on the inside. The main demonstration panel (section of the label most clearly displayed under the customary surroundings of exhibit for sale), must display the product name, identify by illustration the function or nature or descriptive name of the product and display correct report of the net amount of cosmetic contents in the package in terms of measure, weight, numerical count, or a combination of numerical count. The announcement must be different, located in the bottom field of the panel in line usually corresponding to the floor on which the package rests and in a type size commensurate with the size of the container. All label statements essential by regulation must be in English terminology and must be set on the label with such prominence and conspicuousness that they are readily observed, and read by consumers under customary conditions of purchase (labeling of cosmetics in the USA).

4.2 European Union (EU)

European Union defines the cosmetics as “*any substance or preparation intended to be put in touch with the various external functions of the human*”

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body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or maintaining them in safe shape". EU Regulation 1223/2009 (Cosmetics Regulation) reinforces the safety of cosmetic products and streamlines the structure for all operators in the sector. The regulation simplifies procedures to the tier that the internal market of cosmetic products is now a foregone conclusion. The cosmetics regulation adopted in 2009 is replaced by Directive 76/768/EC and substantially updated on numerous occasions. The Cosmetics Regulation provides a robust, globally recognized regime, which reinforces product safety taking into consideration the latest technical developments, including the attainable use of nanomaterials (European Commission, 2015).

The most significant changes experienced by the cosmetics regulation include:

- The Producers are asked to produce a product safety report previous to inserting a product along the grocery store.
- Only cosmetic products for which a natural or legal person is appointed within the EU as "responsible individual" can be placed along the cosmetic industry. The new cosmetics regulation allows the exact recognition of who the responsible person is and clearly outlines the responsibilities.
- The manufacturer will inform its product only once via the EU cosmetic products notification portal (CPNP).
- A responsible individual will bear an obligation to notify serious unwanted effects (SUE) to competent national government agencies. The agencies will also garner information from health professionals and users, and will be appreciative to share the data with other EU Member States. More data on reporting of SUE (European Commission. 2013) is being included. EU Rules are combating misleading information and putting safer cosmetics on EU shelves.
- Preservatives, colorants and UV filters, including those that are nanomaterials, must be openly authorized. Products containing other nanomaterials, not controlled by the Cosmetics Regulation will be the object of full safety measurement at the EU stage. In the list of ingredients nanomaterials are labeled with the word 'nano' in brackets e.g., "titanium dioxide (nano)" (European Commission, 2015).

The necessities of cosmetic labeling under 76/768/EEC directive are:

- The trade name and address of registered office of the producer or of the person employed for marketing the cosmetic product within the Community should be mentioned. It should also carry volume or weight of ware and several safety bars and a distinct recognition of the product reference or number batch number.

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The appearance of expiry date is divided into two types:

1. For products with a least stability of <30 months: the date of least robustness is indicated by “*Best used before the final stage of...*”
2. For products with a minimum constancy of more than 30 months: the period of time for which the product can be used without any harm to the consumer after opening should be mentioned (this information is indicated by a special symbol representing an open cream jar); the ingredient’s list shall be labeled in such a way that the use of ordinary ingredient nomenclature should emerge in the form of downhill order This information must be in the official or national language or languages of the respective member state (*European Union, 2013*).

4.3 India

In India, as per as Drug and Cosmetic Act 1940 and Rules 1945, the cosmetics have been defined as “*any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic*” (Drugs And Cosmetics Act and Rules, 1945). Lack of accomplishment guidelines of the Drug and Cosmetic Act for regulators for issues related to cosmetics such as contradictory approach across authorities in the interpretation of particular issues (Indian Regulatory Scenario, 2013). Cosmetics market is one of the fastest rising retail segments in India, and the booming Indian cosmetics market offers talented opportunities for the US brands. The Indian cosmetic market, which was conventionally a stronghold of a few major players like ponds and Lakme, saw a lot of distant entrants to the market within the last two decades. India allows access of imported cosmetics without any restrictions. India’s import of cosmetics, intermediate raw materials and beauty products such as essential oils is presently around \$400 million (Phookan, 2011). According to Drug and Cosmetics Act in India, both the inner and outer labels should bear the name of cosmetics and manufacturing address. For small size containers the name of principal place of manufacturing and pin code are enough. The outer label should enclose the contents of ingredients used in the manufacturing. The directions to be

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Table 1: Cosmetic regulation in US, EU and India.

Country	USA	EU	INDIA
Authority	FDA	EMEA	CDSCO
Rules and Regulations	Food, Drug and Cosmetics Act	Council Directive 76/768/EEC	Drugs and Cosmetics Act
Labelling	Should comply with the FD&C and FP&L	Based on Council Directive 76/768/EEC	Should comply with part XV of D&C rules 1945
Pre-market approval	Not required	Not required by Cosmetic Directive	Required under state government Licensing
Expiry date	No date required	Date of minimum durability if durability is <30 months. Period after opening if durability is >30 months	Indicated as “Use before date”
Post Marketing Reporting system	Yes. (Voluntary Cosmetic Registration Program)	N/A	N/A
Color additive safety requirement	21 CFR 73, 74, 81, 82	Annex IV of Cosmetics Directive 76/768/EEC	Applicable
Labeling declarations	FDA 21 CFR 701 & 740	Article 6 of Cosmetics Directive 76/768/EEC	BIS and PCRO
Safety warning	On Principal Display Panel	On outer and inner packages	On inner label only
Label language	English	National/Member State	English
Safety	Responsibility of manufacturer.	Manufacturer maintains Product Information File (PIF).	Manufacturer must maintain records.
Nomenclature of colors	Henna is listed in hair color only	Henna is not listed in Annex IV of Directive 76/768/EEC	Henna is not listed as a color

followed for safe use, warning indications, names and quantities of poisonous or hazardous ingredients should be mentioned on the inner label. The label should also carry a characteristic batch number and it's marked by the letter "B" and for soaps the month and year of the manufacturing shall be given in place of the mark "B". This is not relevant to cosmetics weighing 10 g or less for solids or semisolids and 25ml or less for liquid products. On the label, the letter "M" specifies the manufacturing license number (Drugs and Cosmetics Act and Rules, 2013). The similarities and differences in the regulation of cosmetics with respect to USA, EU and India are enlisted in Table 1.

CONCLUSION

Globally, there may be differences in the regulatory systems, however they have a general target of ensuring that the cosmetic products are properly and safe labeled. A considerable difference has been found in cosmetic regulations of different countries like USA, EU and India. Regulatory agencies in the USA and EU have a strong command in their concerned countries, while in India regulations are not so much strict. In the USA cosmetics regulation is authorized by FDA and regulated by Food Drug and Cosmetic Act. Also in Europe, the authority for cosmetic regulation is EMEA and regulated by council directive 76/768/EEC. In India authority for cosmetic regulation is CDSCO and is regulated by Drug and Cosmetics Act and Rules. Currently, the need to harmonize the rules regarding the stability, labeling and safety issue is an important issue. Most importantly, Cosmetic regulations need to be harmonized for safety and quality requirements, so that society can be precluded from being exposed to hormone disruptors, carcinogens and other toxins.

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