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**COMPARATIVE STUDY OF REGULATORY REQUIREMENT AND
RESTRICTIONS FOR SALICYLIC ACID CONTAINING COSMETIC
IN US, EU**

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ABSTRACT

A cosmetic product should be a comprehensive combination of great qualities, including adequate safety, effectiveness, and potency, as well as marketing potential. Many regulatory agencies are doing an outstanding job. These authorities issue rigorous laws that guide the cosmetic industry's manufacturing, importation, packaging, labeling, and other areas of commerce. Producing a product for the market in the USA and European Union is difficult since one must meet the latest rules' safety criteria. The evaluation of cosmetics for protection is complicated by diverse directives from unique regulatory bodies. The FD&C Act and FPLA are both federal laws in the USA that manipulate cosmetics, and the principal controlling authority is the FDA. Also in Europe, the regulatory framework for cosmetics is the EMA's place and is regulated through Regulation No. 1223/2009. In the EU and USA, clinical advisory committees for cosmetic products are known as SCCS and CIR. Safety guidelines are derived from a thorough analysis of all cosmetics' ingredients. This article is an effort to examine the present regulatory status of cosmetic products, the latest rules on salicylic acid-containing cosmetics, and the market conditions in the USA and EU.

Keywords: Cosmetics, Regulatory Requirement, safety, labeling, and packaging, salicylic acid

INTRODUCTION

Cosmetics are the world's fastest growing consumer interest market, with females showing a higher rate of interest than males. For a long time, personal care and beauty products have been used to improve appearance, looks, and perfection. The USA and EU have emerged as the world's leading cosmetics markets. Cosmetics producers in the EU and the USA guarantee product safety before commercialization. Personal care items and cosmetics businesses in the USA and EU work with the greatest scientific and medical experts every day and invest millions of dollars in advanced laboratory equipment and facilities to assure the quality and safety of their products. Certain nations' (US and EU) needs are described in terms of regulatory factors that have an influence on the two terminologies: consumer protection-safety standards and manufacturing company duties. The reason behind this article is to highlight the regulatory landscape and compare the laws for cosmetics in terms of labeling, quality, and product safety with the latest rules on safety criteria for salicylic acid-containing cosmetics in the USA and EU.

COSMETICS IN THE GLOBAL CONTEXT

The worldwide beauty and personal care industry is expected to expand from \$422.72 billion in 2020 to \$558.1 billion by

2026, meaning the market will have grown by CAGR of 4.82 percent. Makeup and colour cosmetics dominate the beauty care market with a 60 percent market share due to the growing female working population, growing fashion trends, and the prevalence of social media outlets such as YouTube, Face book, and Instagram. Because of expanding fashion trends among women and women's financial affordability, nail care has been identified as the fastest growing. Foreign direct investments are on the rise as disposable income rises, population growth and expanding internet penetration. Asia-Pacific is the largest market. North America is next, followed by Europe. Personal care and beauty goods are in great demand in China, which has the world's second-largest revenue and consumption. Companies are always pursuing mergers and acquisitions and the introduction of new items in order to remain competitive in the market [1].

COSMETIC REGULATIONS IN THE USA

In the US, the Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act control cosmetics and the main controlling authority is the FDA [2].

Definition of cosmetic products

The FD&C Act defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or

otherwise when it comes to a person's body for cleaning, enhancing beauty, or changing the appearance." definition are products such as skin moisturizers, perfumes, fingernail polishes, eye and facial makeup preparations, shampoos, lipsticks, permanent waves, toothpastes, and deodorants, hair colors, as well as any material intended for use as a component of a cosmetic product [2].

Good manufacturing practice

FDA published draught recommendations for the cosmetic GMP, which is the main body. These standards are not required to be followed, but the FDA suggests that they be followed in order to ensure that end users receive safe and high-quality products [3].

Pre-market approval

Pre-market approval Except for colour additives, cosmetic items and chemicals FDA approval isn't needed premarket approval [2]. Cosmetic registration is optional in the USA but highly recommended [4]. In The Voluntary Cosmetic Registration Program Cosmetic makers, packers, and distributors can utilize this reporting method. in order to be distributed commercially in the US. Only cosmetics supplied to American consumers are covered under the VCRP. It excludes cosmetics intended solely for professional use, such as those found in beauty salons, spas, and skin care clinics. It also doesn't

apply to non-sale items like hotel samples, complimentary presents, or cosmetics you produce at home and give to friends [3]. Cosmetics importation into the USA does not necessitate a registration number. The FDA has the authority to take legal action against items on the market which violate the law [2].

labeling instructions

The Cosmetic Act The FD&C Act and FPLA are both used by the FDA to regulate cosmetic labeling. When the labeling instructions for a cosmetic product do not meet the act's criteria, it is called "misbranded." Formalized paraphrase Any and all required labeling it is vital to provide information in English [5].

➤ **PDP (primary display panel)** under normal retail display conditions, this is the most likely section of the label to be viewed or inspected [21 CFR 701.10] [5].

On the primary display panel, the following information must be visible:

- An identity statement [21 CFR 701.11] expressing the nature and use of the product by the use of the common or usual name, a descriptive term, a fancy name understood by the public, or an illustration [5].
- [21 CFR 701.13] An accurate statement of the net quantity of

contents, expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure [5].

- **Information panel** This is a non-PDP panel that may show facts on a label that the purchaser is likely to find normally. In most cases, it is not suitable to provide important information near the bottom of the container. Such as the cosmetic component declaration, because it must be visible and apparent [5].

On the Information panel, the following information must be visible:

1. Identify yourself and your company. The maker, packer, or distributor could be this person. The ZIP Code street address, city, state, and country are all included in this information. If the street address appears in a current phone book or city directory, you may omit it [21 CFR 701.12 (a)] [5].
2. Statement of the distributor If the manufacturer's name and address aren't on the label, it must say "Manufactured for..." or "Distributed by..." or something similar. aspects that are realistic. [5]
3. One sort of misleading labeling is the failure to reveal important data,

and a product is misbranded if it fails to do so. Formalized [21 CFR 1.21] paraphrase If a product can be dangerous if used incorrectly, directions for safe usage are an example [5].

4. Statements of caution and warning should be prominent and visible. Certain goods require warning and caution statements, which are outlined in FD&C Act rules [21 CFR section 700] [5].
5. Furthermore, cosmetics that may pose a risk to consumers must be labeled with adequate warnings [21 CFR 740.1]. Flammable cosmetics are one example of a potentially hazardous product [5].
6. Nonetheless, if the item is labeled "For professional use only" or anything similar, and if it is marketed to consumers at retail, the components must be listed in descending order of dominance on an information panel [Section 701.3 of the 21st Century Code of Federal Regulations]. Keep in mind that if the product also happens to be a drug, its labeling must adhere to the standards for the labeling of both OTC drugs and cosmetic ingredients, which are outlined above. Ingredient names, "Color Additives and Cosmetics,"

"Fragrances in Cosmetics," and "Trade Secret" Ingredients are all good places to start learning more [5].

THE EUROPEAN UNION'S COSMETIC REGULATIONS

In Regulation 1223/2009 is the main European legislation governing finished cosmetics items in the EU, according to EC [9, 8]. Chemical and cosmetics rules under the EU's framework are binding on all Member States and implemented at the national level. Compliance is monitored by a competent authority in each EU country [8].

The cosmetics legislation has resulted in a number of notable improvements from the previous Directive 76/768/EC, which was established in 1976, one of which is the [9].

1. Strengthening of safety criteria for cosmetics.
2. The idea of a "responsible person" is introduced.
3. All cosmetic items marketed in the EU are notified centrally.
4. Establishment of a system for reporting major adverse effects (SUE)
5. New guidelines for using Nanoparticles in cosmetics [9]

The responsible person/people are responsible for ensuring that every product he or she sells is on the EU market. It complies with the Cosmetics Regulation's

standards [10]. Scientific committees advise the European Commission on problems concerning cosmetic product safety and allergenic characteristics. The SCCS provides unbiased scientific advice. The Directorate-General for Health and Consumer Protection of the European Commission is in charge of it [10]. SCCS is in charge of examining all cosmetics ingredients sent to them by the EU and certifying safe usage limits or none at all [8].

Definition of Cosmetic Products

The Cosmetics Regulation of the EU is in effect for a clearly defined product category. Cosmetics are defined in 2.1.a as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and mucous membranes of the oral cavity for the sole or primary purpose of perfuming, changing their appearance, protecting them, keeping them in good condition, or correcting body odors." [10]

Good manufacturing practice

The use of CGMP is ostensibly optional, but the Cosmetics Regulation encourages compliance with European Standard CEN 22716:2007. (Similar to ISO 22716) If a product adheres to this standard, which is recognized by the EU as a harmonised standard, it is presumed to be in conformity

with the Cosmetics Regulation's c GMPs requirement. If another standard is used instead of CEN/ISO 22716, the responsible person may be required to demonstrate that the alternative standard provides an equivalent or higher level of rigor.[10]

Pre-market Requirements

The Cosmetics Directive (EU) does not address this issue and does not require cosmetic makers or importers to register, nor does it require pre-market authorization for cosmetic items imported into or manufactured within the EU [10] Color additives, sunscreen active agents, and preservatives are the only ingredients that aren't allowed [8].

In the EU, a full technical dossier on the cosmetic product must be kept on hand and available for inspection by local authorities upon request. The Cosmetic Products Notification Portal (CPNP) receives the information, which includes formula, manufacture, safety evaluation, labelling, and contact information [8].

According to the 1223/2009 (EC) Regulation. There is no requirement for additional notice at the national level inside the EU after a product has been notified in the CPNP. The 1223/2009 Regulation (Article 13) mandates that responsible people and, in some cases, cosmetic product distributors send information to the CPNP regarding the products they place or make on the European market [10].

accordance with the EU regulation 1223/2009" in October 2011 (revision in January 2012). The responsible person (or a delegate) must notify the Commission of cosmetic items containing specific nanomaterials, according to Article 16 of the Regulation. This is different from and additionally to the CPNP (Article 13) notification and it must be completed six months before the product is put on the market [10].

PIF (Product Information Files)

The product information file is a cosmetic product dossier that contains all of the essential information about the finished product, including components. According to Regulation 1223/2009, the responsible person must maintain a product information file for each cosmetic product placed on the EU/UK market, at the address specified on the product label, and make it readily accessible to the competent authority of the EU member state where the responsible person is established. The product information file must be in a language that the local competent authority in the country where the responsible person keeps the cosmetics product information file can understand. The Regulation's Article 11 says the fact that the PIF must include the following information: [10]

1. A brief explanation of the cosmetic item this allows the product details

to be accessed. The file must be clearly attributed to a cosmetic item.

2. A Report on the CPSR
3. Reasoning
4. An explanation of how the approach works in manufacturing, in addition to a message of adherence to excellent manufacturing practices, Manufacturing best practices are Article 8 of the Regulation covers this.
5. Where nature or the law requires proof of the cosmetic product's effect, the cosmetic product's ostensible effect product.
6. Details of the animal being tried out are achieved through the manufacturer. Cosmetics or their components, such as any animal testing conducted in line with a third country's law or regulatory standards. [10]

Labeling and packaging

Labeling and packaging for cosmetics regulation (Article 19) specifies the data that must be printed on the labels of cosmetic products (containers and packaging. A symbol for "minimum durability date" (Annex VII) as well as the hint of chemicals contained as nanomaterials are among the new requirements adopted by the Regulation. When the idea of after-opening durability isn't important, the regulation recognizes

that a "period after opening" is not required: Items provided in containers that do not include single-use products avoid product touch with the outside surroundings, in addition to non-perishable products that won't follow regulatory protection requirements. All cosmetic items must be labeled, whether they are sold in stores, vending machines, mail order, online, applied by experts, or provided in hotels, spas, and other establishments [10].

1. name of the responsible person's name or registered name, as well as address,
2. The origin country of cosmetics exported to the European Union
3. The weight (or volume) of During the time of packing, the nominal content Exceptions: package with a volume of less than 5 g or 5 ML, free samples, and single-application packs
4. The minimum durability date is accompanied by an hourglass symbol or the words "best used before" for products having a minimum service life of over 30 months. The inclusion of a minimum durability date is not required. Unless the concept of post-opening durability is meaningless, the length of time that passes after the opening This indicates that the product is safe to

- use and may be used without causing harm to the customer, which must be specified for such products. An open jar sign must be placed after the time range (in months and/or years, but usually in months as "x M").
5. This data must be given in the native or official language of the particular Member State (s).
 6. A batch number or reference may be utilized to identify the finished cosmetic product. When items are too few to be useful to display such information, it is sufficient to include it solely on the packaging.
 7. The cosmetic product's function is obscure, unless it's obvious from the way it's presented.
 8. Ingredients list (INCI).It is only allowed to be stated on the packaging. First and foremost, the phrase "ingredients" must be used. The ingredients must be listed in a list format in INCI (as in the European Commission's Official Journal Union). When an INCI name isn't available, a term contained within the commonly used general nomenclature can be used.
 9. The material must be provided in the native or official language(s) of the corresponding Member State.
 10. Claims / Misleading Advertisement: Text, names, trademarks, photographs, and figurative or other signals that imply a product has features or functions that it does not have are prohibited under Article 20 of the Regulation. The Cosmetics Directive included a requirement somewhat similar to this one [10].
- Market Surveillance / Cosmetovigilance**
- Non-serious cases must be documented in the PIF as summary information, according to Regulation. Except for those classed as "excluded," serious negative effects must be actively reported to authorities. Person in charge (and Distributor) Country where a significant negative influence occurred
- Initial report: As soon as possible (understood as calendar 20 days) When new relevant information is obtained, a follow-up report is prepared [10].
- COMPARATIVE STUDY OF REGULATORY REQUIREMENT COSMETICS IN US, EU (Table 1)**

Table 1

	UNITED STATES	EUROPEAN UNION
Authority	FDA [2]	EC [8], EMA[10]
Rules and Regulations	FD&C Act and FPL Act [2]	EU Regulation (EC) No. 1223/2009 [9][10]
Pre-market approval	Not required Except for colour additives [2]	It is not required by the Cosmetic Directive, but cosmetic items that are placed or marketed in EU are reported to the CPNP by responsible people. [10]
Good Manufacturing Practice	Cosmetic GMP [3]	CGMP [10]
Safety information	VCRP [4]	PIF [10]
Safety Assessment [ingredients]	CIR Expert Panel [4]	SCCS [10]
Labeling guidelines	FD&C Act and FPL Act [5]	EU Regulation (EC) No. 1223/2009 [10]
Language On Label	English [5]	National/Member State [10]
Expiry Date	There are no laws or regulations requiring cosmetics to have specified shelf lives or have labels that have expiry dates. in the United States. [6]	For products having a minimum lifespan of more than 30 months, the inclusion of a date with the shortest possible lifespan is not required. [10]
Post Marketing surveillance Reporting System	Cosmetic Ingredient Review (CIR), Med Watch [7]	Platform Of European market surveillance authorities for cosmetics (PEMSAC). [11]

RESTRICTIONS FOR SALICYLIC ACID CONTAINING COSMETICS IN US, EU

The cosmetics legislation has resulted in a number of notable improvements from the previous Directive 76/768/EC, which was established in 1976, one of which is that Ron Robinson, a cosmetic chemist, claims salicylic acid is generated from willow bark. Beta hydroxy acids (BHAs) and alpha hydroxy acids (AHAs) are two types of acids commonly found in skin-care products (AHAs). Salicylic acid is a beta-hydroxy acid, which means the hydroxy and acid halves of the molecule are separated by two carbon atoms, versus one carbon atom in an alpha-hydroxy acid. "This structure is essential because it makes salicylic acid more oil-soluble, allowing it

to permeate deeper into the skin's pores," says the researcher. Salicylic acid is a keratolytic exfoliator that works best on blackheads and whiteheads while also helping with dandruff [12].

USA

In USA Salicylic acid is the most widely used BHA in cosmetics nowadays. The CIR Expert Panel has review of the most commonly used cosmetic ingredients in USA [13].

The safety of salicylic acid used as a cosmetic ingredient has been evaluated by both the cosmetic industry and FDA. At a meeting in February 2000, the Cosmetic Ingredient Review (CIR) Expert Panel, the cosmetic industry's independent body for reviewing the safety of cosmetic ingredients, reached the tentative

conclusion that the use of salicylic acid related substances in cosmetics is safe as used when formulated to avoid irritation and when formulated to avoid increased sun sensitivity." CIR added that "when sun sensitivity would be expected, directions for use [should] include the daily use of sun protection." [13]

FDA advises precautions and Restrictions

- Babies and children should not be exposed to BHA-containing products [13].
- Use sunscreen if you're going to use a BHA product [13]
- Cosmetic makers should test their goods in order to comply with the CIR requirements. If they enhance sensitivity to damaging UV radiation from the sun [13]
- The FDA requires specific product instructions for this active ingredient, which should be carefully considered when designing packaging and marketing materials for any product that monograph covers. FDA's monograph permits salicylic acid to be used as a single active ingredient in concentrations ranging from 0.5 percent to 2.0 percent [14]

EU

In the EU, the European Commission released a corrigendum to its November

2019 revision of Regulation 1223/2009 (EC) (Cosmetics Regulation) on March 12, 2020. Salicylic acid, a well-known cosmetic component recognized for its antidandruff, hair and skin conditioning, and keratolytic qualities, has received an upgrade [15, 17].

The corrigendum states that salicylic acid should not be used for anything other than cosmetic preservation. The following substances are acceptable:

- ✓ For hair rinses with a maximum awareness of 3%, [15-17]
- ✓ Eye shadow, eyeliner, body lotion, lipstick, and roll-on deodorant mascara are exempt with a maximum attention of 2%. [15-17]

The Corrigendum then explains further that salicylic acid should not be used in the following situations:

- ✓ Applications wherein inhalation might also additionally disclose the lungs of the cease user [15-17].
- ✓ Oral products [15-17].
- ✓ Products for kids Beneath Neath three years of age [15-17]
- ✓ Salicylic acid is allowed in products not intended for children under the age of three as a preservative with

the highest concentration of 0.5 percent [15-17].

CONCLUSION

The purpose of this article is to demonstrate the variations in cosmetic regulations throughout two major nations regarding its definition, manufacturing requirements, pre-marketing approval, labelling guidelines, post-marketing reporting and surveillance system, safety criteria, and assessment of salicylic acid-containing cosmetics. When it comes to manufacturing requirements in both the US-FDA and EU-EMA, the use of CGMP is for manufacturers ostensibly optional, and distributors can utilise the VCRP reporting method. to be distributed commercially in the US. In the EU, a full technical dossier on the cosmetic product must be submitted through the Cosmetic Products Notification Portal (CPNP). When it comes to safety, the CIR Expert Panel in the USA and SCCS in the EU review all cosmetics ingredients which are registered in VCRP and CPNP and declare safe usage levels. This article additionally stressed the safety criteria guidelines for salicylic acid-containing cosmetics given by CIR (USA) and SCCS (EU). The general rules for cosmetics regulation in both markets are a manufacturer's responsibility for the safety of products. Based on postulated safety guidelines However, the strict rules governing the use of cosmetics in each

country or jurisdiction have one common goal: to protect consumers by providing safe ingredients and finished products.

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