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REGULATORY ASPECTS AND SAFETY USE OF COSMETIC PRODUCT IN EUROPEAN UNION

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ABSTRACT

Cosmetics Law (EC) No. 1223/2009 of the European Union (EU). Various regulatory bodies around the world, all of which have their own rules and regulations, regulate the safety of cosmetic goods. Among its several values, the European Union (EU) has been aiming for many decades, enshrined in the EU Directive, to ensure that cosmetic products do not cause harm to customers. For each and every cosmetic product placed on the EU consumer market, the Directive requires a safety assessment. The general regulations relating to chemicals used in the EU are applicable to cosmetic products, where several aspects of the toxicological profile must again be defined and checked. The main objectives of this regulation are to create a set of rules that comply with all cosmetics and to ensure a high level of protection for human health. Regulations directly affecting the manufacture and sale of cosmetic products include: cosmetic definition, licensing, labeling, substantiation of safety, stability studies and legal authority.

Keywords: Cosmetic regulation, Safety assessment, CPNP, Responsibility

INTRODUCTION

The single market - the term used to describe the free movement between the Member States of the European Union of products, money, citizens and services - is a pillar of the European Union. Similar regulations must be in effect in all the Member States in

order for it to function for a particular product market **[1]**.

Through strict legislation, the United States (US) and the European Union (EU) all work to ensure the protection of cosmetics for consumers. The cosmetics sector in the United States is controlled by the U.S. Under the Federal Food, Drug and Cosmetic Act, passed in 1938, the Food and Drug Administration (FDA) has been given broad regulatory authority. The Member States of the European Economic Community (now called the European Union - EU) voted at the beginning of the 1970s to harmonize their national cosmetic laws with a view to enabling cosmetic products to circulate openly within the Community on the basis of generally accepted safety standards **[1]**.

The Cosmetics Directive was adopted on 27 July 1976 as a result of various consultations between experts from all Member States and published in the Official Journal of the European Communities (OJEC) on 27 September 1976 under reference 76/768/EEC.

Cosmetics suppliers in both the United States and the European Union maintain the quality of cosmetics before they are put on the market, list all ingredients on the product label and comply with any limitations levied on cosmetic ingredients and products. As part of the safety assessment, any possible risk from a substance is evaluated **[1]**.

Although harmonizing the legal principles and criteria for cosmetics across the EU, it was also important to transpose the EU Cosmetics Directive into the national law of each Member State in order to become local-level relevant legislation.

A cosmetic product made available on the market shall, when used under usual or fairly foreseeable conditions of use, be appropriate for human health.... The purpose does not vary in this respect from that of the preceding Directive. The legislation contains some other provisions, but for the purposes of this account, we have concentrated only on factors that matter to consumers.

A 'cosmetic product' means any substance or preparation intended for placing in contact with the various external parts of the human 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 principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odors.

The products to be considered as cosmetic products within the meaning of this

definition are listed in Annex I (76/768/EEC).

LEGISLATION OF COSMETICS AUTHORITIES IN EU

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products is the basis of the EU cosmetic legislation (Cosmetics Directive). As in the U.S., it is the duty of suppliers to ensure that cosmetic products comply with the legislation before they are marketed **[2]**. It is the duty of the manufacturer or importer of cosmetics to prove that the substance is safe for its intended use. Regulations are applied at national level and there is an official body in each EU country that is responsible for ensuring compliance.

EUROPEAN UNION COSMETICS REQUIREMENTS

In each EU country, national agencies are responsible for updating safety evaluations and inspecting goods currently on the market. Legislation on cosmetics mandates that any cosmetic product put on the market in Europe should be safe to use. The EU Regulation 1223/2009 on cosmetics entered into force in 2013 and affects 31 European countries **[3]**.

- Safety of Raw Materials and Ingredients
- Good manufacturing practices
- Invigilating of cosmetic market

These values translate into cosmetic brand criteria (non-exhaustive list):

- Designate a Responsible Person (RP)
- Prepare a Product Information file (PIF) including a Safety Assessment
- Respect the Good manufacturing practices (GMP) for cosmetics
- Comply with Labeling and Packaging requirements
- Ensure notification via the Cosmetic Products Notification Portal (CPNP)

SAFETY AND RESPONSIBILITY OF COSMETIC PRODUCT [4]

A cosmetic substance put on the market shall be safe for human health and ordinarily used or fairly foreseeable conditions of use, taking into account, in particular, the appearance, including compliance with Directive 87/357/EEC, the marking, the directions for use and disposal, as well as any other signs or details given by the individual responsible **[4]**.

Responsible parties shall ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19(1), (2) and (5) and Articles 20, 21, 23 and 24.' The RP is responsible for ensuring that all duties relating to product conformity have been satisfied prior to the placement of the product on the European market and consequently serving as a point

of touch for Cosmetic-Vigilance in Europe. A competent responsible person should serve as a consultant allowing for the promotion of any compliance in EU cosmetics.

- Formula verification- review for restricted, prohibited ingredients, etc.
- Support collecting, verifying and compiling documentation required for the Product Information File
- Creation and validation of the Product Information File
- Verification of Safety Testing
- Identification of missing Safety Testing & EU Accepted Protocols
- Guidance on labeling and language requirements
- Advice on claims & proper substantiation
- Guidance on compliance with the No Animal Testing, GMP, CMR
- Pre-Market Notification

Once products have been registered (notified), the EU Responsible Person should also provide:

- Ongoing Regulatory updates & EU Market Consultancy
- Post-Marketing Surveillance: reporting of Serious Undesirable Effects (SUE), support regarding any EU Competent Authority requests, corrective measures,
- Immediate corrective measures, withdrawal/recall if appropriate in case of non-compliance.
- Immediate information to competent authorities (CA) and other economic operators in case of risk to protection of human health.

GOOD MANUFACTURING PRACTICE [5]

A cosmetic law according to Article 8 of the European Directive 76/768/EEC cosmetic manufacturing facilities to function in compliance with sound production standards (GMP) this does not pose a threat to goods that are formulated or processed in standard production facilities. When preparing the cosmetic product in situ (i.e. at the retailer's store), however, the task is considerable. When a device is used, the device becomes a "production facility" and can thus conform to sound production standards. This ensures that the unit should be routinely adjusted and optimized to ensure precision and continuity in the quantities dispensed. Tools should also be maintained in a good hygienic state, and to ensure proper usage and servicing, persons using the system should be properly trained. Reports should be geared towards ensuring that the customer is adequately qualified, dispensing materials are calibrated and the

equipment is safe if no system is used, but a person prepares the substance at the market.

PRODUCT INFORMATION FILE [6]

The liable person shall keep the product information file (PIF) containing the related protection report readily available at the address indicated on the label to the competent authorities of the Member State concerned **[6]**.

The information needed in the product information file (PIF) is as follows:

- A description of the cosmetic product which enables the PIF to be clearly attributed to the cosmetic product
- The cosmetic product safety report
- A description of the method of manufacturing and a statement on compliance with good manufacturing practice
- Where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product
- Data on animal testing performed by the manufacturer, his agents or suppliers.
- Labeling (taking into account the primary packaging and outer/ secondary packaging)
- Data on Serious Undesirable Effects
- And more…

The PIF shall be stored at the address specified on the label by the responsible individual (who must signify his address within the European Community) for a period of 10 years after the last batch has been put on the market. The PIF should be stored in a protected storage location, readily available in electronic or other format to the competent authorities.

The PIF shall be stored at the address specified on the label by the responsible individual (who must signify his address within the European Community) for a period of 10 years after the last batch has been put on the market.

In order to fulfill the specifications laid down by Regulation 1223/2009, the RP must ensure that the PIF contains all the required paperwork. The duty of the RP is also to ensure that the compliance of the artwork and the statements on the packaging is complied with and that the terminology of the PIF is readily interpreted by the competent authorities and, where appropriate, to correct the documents inside the PIF.

In addition to the regular PIF review, which has almost 30 years of experience with EU legislation, it would be pleased to provide assistance for the collection of the PIF and the appointment of safety assessors as well.

COSMETIC PRODUCT SAFETY REPORT (CPSR) [7]

Each cosmetic product put on the market should be safe to use and should be subject to an expert safety review. There are two sections of the cosmetic product safety report: safety details and safety evaluation. The primarily includes:

- Quantitative and qualitative composition of the cosmetic product
- Physical/chemical characteristics of the cosmetic product with the stability reports under reasonably foreseeable storage conditions
- Microbiological specifications of the product and results of the preservation challenge test
- The purity of the substances and mixtures used in the product and the purity and stability characteristics of the packaging material
- Information on the exposure of the cosmetic product with the toxicological profile of the substances
- Available data on the undesirable effects to the cosmetic product.[7]

SAFETY ASSESSMENT [8]

In order to show that a cosmetic product complies with Article 3, before putting a cosmetic product on the market, the liable person shall ensure that, on the basis of the relevant facts, the cosmetic product has undergone a quality review and that a cosmetic product compliance report is drawn up in compliance with Annex I of Regulation (EC) No 1223/2009 on cosmetic products **[8]**.

Only a person with formal qualifications who has completed a university course of theoretical and clinical training in pharmacy, toxicology, medicine or a related discipline may carry out a cosmetic product safety evaluation.

SAMPLING AND ANALYSIS OF COSMETIC PRODUCT [9]

In other words: precision of findings against proven testing methods; validity of testing to accurately reproduce real-world conditions; and continuity. EU law requires that "the sampling and analysis of cosmetic products must be carried out in a reliable and reproducible manner." In essence, when your cosmetics product is kept to the above requirements, you focus on your production plants to be able to perform your design correctly and reliably in a way that keeps each unit of your batch safe for use and safe from factory pollutants **[9]**. To ensure that your product is safe for your clients and complies with the applicable legislation.

COSMETIC PRODUCT NOTIFICATION PORTAL (CPNP)

The cosmetic product on the market, the responsible person shall notify a list of information relating to the cosmetic product to the Commission, through the Cosmetic Product Notification Portal. The Regulation states that the designated Responsible Person (or EU Brand Owner) is required to submit certain information about cosmetic products and their product specifications to the CPNP if they intend to make them available on the EU Market **[10]**. In some cases, cosmetic product distributors are also required to follow these steps – such as in the case of changes to labeling and translations. EU Responsible Person(s) and EU Brand Owners have access to the CPNP for Notification. Submission to CPNP under Regulation (EC) No 1223/2009, you are obliged to make a new product notification before the product is placed on the market and after having fulfilled all of the provisions of the Regulation. No moment is specified, providing it is before circulation begins **[11]**. The exception to this is the notification of products containing nonmaterial's, which must be done six months prior to commercialization.

LABELING REPORT [12]

The labeling report (e.g.: container, outer packaging and inserts) of a cosmetic product must reflect the product information file of the cosmetic product. As such the labeling can only be created after the product filing and reviewed by the responsible person.

The final labeling of the cosmetic product must contain as following information:

- Full commercial name (Brand name, commercial name, functions),
- Product Function is not required when the product presentation clearly shows the function, Particular precautions for use (must be translated) When impossible, for practical reasons, to have the precautions for use appear on the product container and outer packaging, then this information may be listed in an insert / leaflet only. In this case the "open book symbol" shall appear on the container or the outer packaging of the product.
- Ingredients list should perfectly match those mentioned in the safety assessment, in descending order with each ingredient's INCI denomination, including allergen and Color Index numbers (CI)
- Expiry date (minimum 30months durability)
- Responsible person name and address (recommended),

- Manufacturer Name and Address - recommended
- Batch number: When impossible, for practical reasons, to make it appear on the product container, it may appear only on the outer packaging
- Product country origin Made in … "only if manufactured outside the European Union.
- Nominal quantities the nominal content at the time of packaging, given by weight or by volume, except for packaging containing less than 5 grams or 5 milliliters, free samples and single application packs.

SERIOUS UNDESIRABLE EFFECT OF COSMETICS (SUE) [13]

Undesirable Effect (UE) Cosmetic Regulation as an "adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product" The regulation differentiates Serious Undesirable Effect (SUE) that "causes (temporary or permanent) functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death.

Section A of a Study on Cosmetic Protection. Indeed, as set out in Annex I to Cosmetic Regulation 1223/2009, all available EU and SUE data concerning a cosmetic product or, where applicable, other cosmetic products should be registered. This entails evidence from statistics **[13]**.

The extent of the contact of undesirable effects and severe undesirable effects is established by Article 23 of Regulation 1223/2009. As a responsible individual or provider, you must inform the relevant authorities of the Member State involved and provide: The EU Cosmetic Legislation specifies that, upon request, current data concerning the UE and SUE must be made available to the public by all reasonable means.

NONMATERIAL [14]

A high degree of human health safety is assured for any cosmetic product containing nonmaterial's Furthermore, cosmetic products containing nonmaterial's other than dyes, preservatives and UV-filters and not otherwise prohibited by Regulation (EC) No 1223/2009 are subject to an additional process. They request that the CPNP be explicitly informed six months before marketing (Art. 16(3)). The European Commission shall approve certain classes of substances, i.e. dyes, preservatives and UV filters, including those which are nonmaterial's, prior to their use in cosmetic products. The SCCS judgment, which

analyses the toxicological evidence submitted, precedes this authorization.

CONCLUSION

Every day in Europe, cosmetic and personal care products firms collaborate with leading science and medical professionals and spend millions of dollars in specialized testing instruments and laboratories to ensure the quality and safety of cosmetic products. When seeking to sell their goods around the world, the beauty industry faces many obstacles. There are numerous and various multinational enterprises, all of which face regulatory problems. The Cosmetic Control Authority for Europe is EMEA and is governed by Council Directive 76/768/EEC. There are a lot of gaps between the EU and US cosmetics laws. A cosmetic law according to Article 8 of the European Directive 76/768/EEC cosmetic manufacturing facilities to function in compliance with sound production standards (GMP) Pursuant to Regulation (EC) No 1223/2009, the cosmetic product notification portal shall inform you that you are expected to make a notification of a new product before the product is put on the market and after all the requirements of the Regulation have been fulfilled.

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