

## **(Guidance and Requirements of Cosmetic product Notification)**

### **Volume No. 2**

Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

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## Definitions:

The following words and expressions- as they appear in this Law- meaning as stated, unless the context otherwise requires:

- **Cosmetic Products:** Any cosmetic product that contains one or more substances prepared for external usage of the human body parts including skin, hair, nails and lips or on the external parts of genital organs, teeth or mucous membranes of the oral cavity for the purpose of cleaning, perfuming, protecting and keeping them in a good in good condition, changing or improving their appearance or changing or correcting the body odor.
- **Notifying:** Restraining cosmetic products in the cosmetic products record after it is approved by the Authority.
- **Notifier:** Natural or legal person who lists cosmetic products by his name in the Authority
- **Manufacture:** The local establishment where the cosmetic product is made.
- **Warehouse:** A place that is licensed by the Authority for storing, distributing and trading cosmetic product.
- **A Producing Company:** A company that manufacture product, contracting with others to manufacturing product, marketing or distributing the product.
- **Recall:** Procedures or measures taken by the notifier voluntarily or upon request by the Authority to restore the acquisition of the unsafe cosmetic product for the consumer or contrary to this Law and forbidding its circulation.

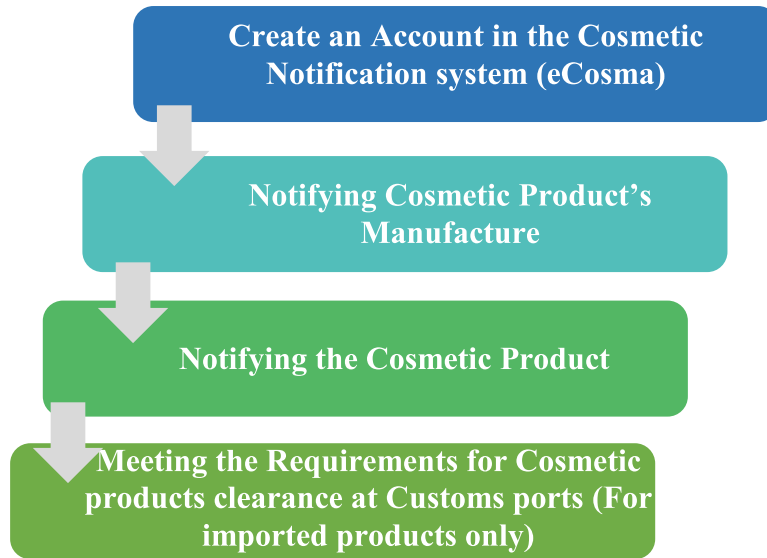
## Introduction:

In accordance to the Law of Cosmetic Products promulgated by Royal Decree number M/49 on 18/6/1436 AH. and its issued by SFDA Board of Directors which include to clarify and explain in detail as the Law provides and its Implementing Regulation in regards of listing cosmetic products in the Listing Law.

As provided in Article Six to not import or trade a cosmetic product in Saudi Arabia unless it is listed in the Electronic System for Listing Cosmetic Products as listing aims to organize import, trade and market cosmetic products in Saudi Arabia. It also aims to provide integrated database of all marketed cosmetic products in Saudi Arabia, in addition to the data of their importers and local manufacturers.

## 1. Process of Notifying Cosmetic Products in Saudi Arabia

Notifying is listing cosmetic products in the SFDA records via Cosmetic Notification system (eCosma) and does not mean the product safety has been evaluated by SFDA. Notifying aims to create a comprehensive database of cosmetic products that manufactured locally or imported by recording them in SFDA records and the notifier (responsible person) shall be in compliance with the validity of the information entered as well as the safety of the products.



For more on how to use the Cosmetic notification system for product notification and manufacture licensing, please click or scan the following barcode:



## 2. Requirements of Cosmetic Product Notification:

### 2.1 Product's Label:

- It is required when submitting cosmetic product notification to attach a clear image (one or more) of the product from all sides that show its information and substitutions in visible and readable way. The image shall include the internal and external product label and its internal brochure, if any. The images can be presented in one of the following forms: PNG, JPG, TIFF and PDF.
- The cosmetic product label shall be in conformity with the Cosmetic Products Legislation and the Standard of Safety Requirements for Cosmetic Products and personal care No. GSO1943/20016. The Gulf Standard GSO1943 can be obtained by SFDA Standard Online Store through clicking or scanning of the following barcode:



- The product label must contain its own barcode and shall be entered in cosmetic notification system with consideration to product's size and colour.
- Recallss is one of the criteria a which determine the product is a cosmetic or not it includes everything written or mentioned in the inner, outer packaging of the product, on any poster, brochure attached thereto or in any form of publicity and advertising and it may be a word, sentence, paragraph, image or implication Cosmetic Products – Technical Regulation of cosmetic and personal care product recallss can be obtained by SFDA Standard Online Store through clicking or scanning of the following barcode:



## 2.2 Ingredients:

- Adding product components in the Electronic System is one of the requirements for cosmetic notification process as which all the active and inactive ingredients, role and exact concentrations should entered in the system. The notifier (responsible person) must assure the validity of the entered data and the safety of the product. Note that the Authority published a list of the banned products and restricted use in the cosmetic products in addition to a list of preservatives and colourings items allowed in the Cosmetic Products Website in accordance to article four of the Implementing Regulation of the Cosmetic Products Law.
- Note that it is possible now when applying for a notification request of the product, to attach a file contains a list of product ingredients with all ingredients (manually) submitted via the Electronic System as determined by SFDA.

## Adding a component to the Notification Database:

If desired to add a new component that is not available in the (eCosma), the notifier shall know the name of ingredient (INIC) Nomenclature and its CAS number then send it through e-email titled “Adding Cosmetic Ingredients to the Database (eCosma)” to the email address: [eCosma@sfd.gov.sa](mailto:eCosma@sfd.gov.sa)

## 2.3 Required Documents:

### 2.3.1 Required Documents to Create an Account:

- A copy of the main commercial registration of the establishment.
- Photo of the national identity of the owner of the establishment “institutions”/incorporation contract “Companies”.
- A copy of the investment authority license if the company is foreign or mixed.
- A copy of the national ID or residency of the person responsible for following up the application with the Authority.
- A copy of the legal agency or certified authorization from the Chambers of Commerce to the person responsible for following up the application with the Authority.

### **2.3.2 Required Documents to List the Establishment According to the responsible person:**

You can see “appendix 1” to know the mechanism and required document to notify cosmetic establishment.

#### **Authorization letter requirements:**

1. Name of the delegated establishment, its address and its commercial registration number.
2. Name of the authorized establishment, its commercial registration number and address.
3. The authorization shall be printed on the official paper of the establishment that made the delegation and stamped with it.
4. Name and signature of the official in the establishment that carried out the delegation.
5. Authorization attestation by the competent authority.

### **2.3.3 Cases that are Exempt from the Requirement of Licensing Cosmetic Products:**

1. Imported for direct supply of guest houses, hotels and hospitals.
2. Imported “Retailer” and supplied directly to his shop.

### **2.3.4 Required Documents of Notifying Cosmetic Product:**

- A copy of the product lable includes all its information.
- A copy of the internal bulletin of the product, if any.
- A List of product components with concentration and roles

### **2.3.5 Required Documents to clearance Cosmetic product:**

You can view the required documents to clearance cosmetic products through the outlets on the website of the Authority by clicking or scanning on the following barcode:





### 3. Responsibilities of the Notifier:

The notifier shall be responsible and bounded by follows:

- The safety of the cosmetic product.
- The cosmetic product shall not cause any harm to the health of the user under normal circumstances in accordance with the guidance of use and disposal shown in the product label data.
- The Authority shall be informed in case of damaged caused by the cosmetic product, error in manufacture or recalls in any country.
- Maintain the cosmetic product information file (PIF) and submit it to the Authority upon request. The specification of the produce information file of cosmetic products SFDA.CO 6000:2020 can be obtained through the electronic store for the specifications of SFDA by clicking or scanning the following barcode:



- The Authority shall be informed in case of modification to the cosmetic product.
- Document selling cosmetic product as a wholesale.
- The Authority shall be informed by any misuse of the cosmetic product.
- Provide the Authority with the results of the analysis that proves the conformity of the cosmetic product with the specifications upon request.
- Compliance with the Technical Regulations and circulars issued by the Authority.
- Follow up on recall or withdrawal of products from all sales and distribution outlets, whenever necessary.
- Validity of data submitted to the Authority.
- Validity of the regulatory path of the notified product according to the definition of cosmetic product and the FDA product classification Guideline by clicking or scanning of the following barcode:



#### 4. Process of Updating a Cosmetic Product Notification:

Cosmetic notification system (eCosma) allows the notifier to update the product notification as long as the modification does not impact or change the product characteristics or substitutions, otherwise the notifier should resubmit the product notification request.

The following table shows where the product should be updated or re-listed:

Adjustment*	Product Update	New Product
Product image (change design – adding logo)	√	
Trade Name		√
Product Name		√
The Manufacture		√
Producing Company		√
Importer		√
Ingredients (adding/removing ingredients changing ingredient's role/concentration)		√
Package Volume	√	
Barcord Number	√	
Storage Conditions	√	
Protection Instruction	√	
Product's Indications		√

\*Measuring updated product or submitting it as a new request in contrary to what was mentioned in the table above in accordance with the Authority convenient view.

#### 5. Mechanism of Renewing Cosmetic Product Notification:

According to article (6) in cosmetic product law, the notifier (responsible person) shall renew the product notification at least 90 days before its expiration date.

## Appendix 1

### Notify Cosmetic Products Manufacture

This appendix is prepared to explain the required fields and documents necessary for listing manufacture that defined as establishment in which the cosmetic product is manufactured in.

To enter the cosmetic notification system, please click on the icon:

بيانات المصنع / Manufacture Information
1

1 Manufacture Information

2 Manufacture Address

3 Contact Person Information

4 Production Lines

English Manufacture Name

Arabic Manufacture Name

Manufacture Nationality

(Select) ▼

3

Save as Drafts
Cancel
Next

Enter the manufacture name in English	أدخل اسم المصنع باللغة الانجليزية	*1
Enter the manufacture name in Arabic	أدخل اسم المصنع باللغة العربية	*2
Choose the nationality of the brand owner company	اختر جنسية الشركة المالكه للعلامة التجارية	*3

\* Mandatory fields
\* حقول إلزامية

**Manufacture Address / عنوان المصنع** 2

1 Manufacture Information

2 **Manufacture Address**

3 Contact Person Information

4 Production Lines

Country (Default)  1 City  2

Province  3 District  4

Street  5 Building Number  6

Phone  7 Fax  8

Web Site  9 Zip code  10

Email  11 P.O. Box  12

Latitude  13 East  14

Copy of Authorization letter for marketing in KSA  15 Copy of GMP certificate in country of origin  16

License number in country of origin  17

Copy of license certificate in country of origin  18

Enter the manufacture address: Country	أدخل عنوان المصنع: الدولة	*1
Enter the manufacture address: City	أدخل عنوان المصنع: المدينة	*2
Enter the manufacture address: Province	أدخل عنوان المصنع: المنطقة	3
Enter the manufacture address: Area/District	أدخل عنوان المصنع: الحي	*4
Enter the manufacture address: Street	أدخل عنوان المصنع: الشارع	5
Enter the manufacture address: Building Number	أدخل عنوان المصنع: رقم المبنى	6
Enter the phone number in the international format	أدخل رقم الهاتف (أدخل الرقم بمفتاح الدولة والمنطقة)	7
Enter the fax number in the international format	أدخل رقم الفاكس (أدخل الرقم بمفتاح الدولة والمنطقة)	*8
Enter the manufacture's website	أدخل الموقع الإلكتروني للمصنع	*9
Enter the Zip code of the manufacture	أدخل الرمز البريدي	*10

Enter the E-mail address of the manufacture	أدخل البريد الإلكتروني	*11
Enter the P.O. Box of the manufacture	أدخل الصندوق البريدي	*12
Enter the manufacture coordinates: North	أدخل إحداثيات المصنع: جي بي اس - شمال	*13
Enter the manufacture coordinates: East	أدخل إحداثيات المصنع: جي بي اس - شرق	*14
Attach a certified copy for the marketing authorization letter from the manufacturer or the entity where the products are imported from, an exception is the contractual manufacturing where the manufacturing contract should be attached here, and if it's an owned manufactory, attach the manufacture license	استخدم هذه الأيقونة لإرفاق نسخة مصدقة لخطاب التفويض من المصنع/المنشأة المستورد منها، ويستثنى من ذلك التصنيع التعاقدى حيث يتم إرفاق عقد التصنيع، وإذا كان المصنع مملوك للمنتج إرفاق رخصة المصنع.	*15
Attach copy of the GMP certificate in the country of the origin, a statement should be attached in case of its absence	استخدم هذه الأيقونة لإرفاق شهادة التصنيع الجيد إن وجدت، أو يتم إرفاق إفادة بعدم وجودها	*16
Enter the number of the manufacture license or the license of the entity where the products are imported from	أدخل رقم رخصة المصنع/المنشأة المستورد منها في بلد المنشأ	*17
Attach the local manufacture license or the commercial register of the entity where the products are imported from	استخدم هذه الأيقونة لإرفاق نسخة من رخصة المصنع/سجل المنشأة المستورد منها في بلد المنشأ	*18

\* Mandatory

\* حقول إلزامية

**Contact Information / بيانات التواصل** 3

1 Manufacture Information

2 Manufacture Address

3 Contact Person Information

4 Production Lines

English Full Name  1

Arabic Full Name  2

Job Title  3

Authorization Letter  4

Mailing Address

Email  5

Mobile  6

Phone  -  7

Fax  -  8

Enter the name of the contact person in Arabic	أدخل اسم الشخص المفوض للتواصل باللغة العربية	*1
Enter the name of the contact person in English	أدخل اسم الشخص المفوض للتواصل باللغة الإنجليزية	*2
Enter the job title of the contact person	أدخل المسمى الوظيفي للشخص المفوض للتواصل	*3
Attach a copy of authorization letter	ارفق صورة من كتاب التفويض	*4
Enter the E-mail address of the contact person	أدخل البريد الإلكتروني للشخص المفوض للتواصل	*5
Enter the mobile number of the contact person	أدخل رقم الجوال للشخص المفوض للتواصل	*6
Enter the phone number of the contact person	أدخل رقم الهاتف للشخص المفوض للتواصل	*7
Enter the fax number of the contact person	أدخل رقم الفاكس للشخص المفوض للتواصل	*8

\* Mandatory

\* حقول إلزامية

**نوع المنتج / Product Type**
4

- 1 Manufacture Information
- 2 Manufacture Address
- 3 Contact Person Information
- 4 Production Lines

**Production Lines** 1

- Skin Oil
- Skin Gel
- Skin Paste
- Skin Capsule
- Skin Powder
- Skin Patch
- Skin Soap) Liquid(
- Make-up or Make-up Removal (Liquid)
- Lip Products (Solid)
- Deodorant or/and Antiperspirant (Solid)
- Non-Hydroalcoholic Perfumes
- Hair Oil
- Hair Cream or Lotion
- Hair Paste
- Hair Capsule
- Hair Powder
- Eye Kohl (Solid)
- Eye Liner (Liquid)
- Eye Mascara
- Nail Products (Liquid)
- Nail Stick
- Tooth Cleansing) Powder/Salt(
- Breath Spray

- Skin Cream or Lotion
- Skin Petroleum Gel
- Skin Aerosol
- Skin Ampoule
- Skin Pad
- Skin Mask (Including Face, Hand and Foot)
- Skin Soap )Solid(
- Make-up or Make-up Removal (Solid)
- Lip Products (Liquid)
- Hydroalcoholic Perfumes
- Tissue Wipe (Except Antiseptic Wipe)
- Hair Shampoo and/or Conditioner
- Hair Gel
- Hair Aerosol
- Hair Ampoule
- Eye Kohl (Liquid)
- Eye Liner (Solid)
- Eye Shadow
- Eye Mask Pad
- Nail Products (Pad)
- Toothpaste
- Mouth Wash
- Tooth Stick

Save as Drafts
Cancel
Back
Preview

Choose the type of the manufactured product

**\*1** اختر نوع المنتج المصنع

\* Mandatory fields

\* حقول إلزامية