

## **Implementation of the Customized Cosmetics System**

Definition: A cosmetics product that can be customized based on personal preferences or skin type by a Customized Cosmetics technical manager at a retail store. It can be allocated in a desirable amount or added/mixed with other ingredients, colorants, and fragrances as determined by the Ministry of Food and Drug Safety (MFDS).

BEFORE implementing the system	Consumers needed to select from cosmetics products that were uniformly created at a manufacturing plant.
AFTER implementing the system	Consumers have personal choice to select fragrance, colors, amount (size), functional, or other options of the cosmetics products.

## **Purpose of Adopting the Customized Cosmetics System**

As our culture and society shift to emphasizing individual choice, the system is adopted to satisfy both the diverse demands of consumers with customized products and personalized services, and safety.

Previously, cosmetics laws prohibited mixing or dividing cosmetics into small proportions at retail stores. Thus, an additional law needed to be enacted to allow the use of a Customized Cosmetics System.

\* Requested for introducing the system at the "9<sup>th</sup> External Trade Investment Organization" (February 17, 2016).

## **Implementation of Pilot Project Throughout Korea**

Pilot project was operated before the establishment of the basis of the Customized Cosmetics System.

- Period: March 21, 2016 – March 13, 2020
- Subject of interest: main stores of responsible person (brand holder), cosmetics stores at duty-free shops, etc. (Around 58 locations)
- Application: ingredients + mixed with additives or allocated into small amounts
  - Fragrance, skincare, or makeup products

### Legal Systems Related to Customized Cosmetics

Cosmetics Act	① Definition of Customized Cosmetics ② Establishment of new business ③ Terms of compliance ④ Training for customized cosmetics technical managers (who examine the process of compounding and subdividing) ⑤ Qualification exam for customized cosmetics technical managers * Enacted on March 13, 2018; implemented on March 14, 2020
Enforcement Decree of the Cosmetics Act	(no revisions)
Enforcement Rule of the Cosmetics Act	① Requirements/process for notification of manufacturing business or notification of change ② Terms of compliance for sellers ③ Subjects for training

	<p>④ Product returns, indications, and other processes of Customized Cosmetics</p> <p>⑤ Specific plans for operating qualification exams (e.g., frequency, subjects of the material, testing methods)</p> <p>⑥ Terms of compliance and standards for agencies administering qualification exams</p> <p>* Pre-announcement of legislation on August 19, 2019; implemented on March 14, 2020</p>
<p>Notifications - 'Regulations on cosmetics safety and standards, etc.'</p>	<p>Designating applicable ingredients in Customized Cosmetics</p> <p>- All substances can be used in Customized Cosmetics except the three following types of material.</p> <p>① Forbidden materials</p> <p>② Materials with limited use</p> <p>③ Some designated functional ingredients which are not prequalified or submitted as functional cosmetics</p> <p>* Enacted on October 17, 2019; implemented on March 14, 2020</p>
<p>Guidelines for selling Customized Cosmetics</p>	<p>① Definition and applications of Customized Cosmetics</p> <p>② Notification of Customized Cosmetics business</p> <p>③ Application of material and ingredients in Customized Cosmetics</p> <p>④ Terms of compliance of Customized Cosmetics sellers</p> <p>⑤ Sanitation and facility standards of Customized Cosmetics businesses</p>

	⑥ Management plans of compound regulators in Customized Cosmetics Indication of Customized Cosmetics
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## **Notification of Customized Cosmetics Business**

- (Notification) Sellers who wish to sell Customized Cosmetics need to notify the Regional Office of Food and Drug Safety with the required documents.

\* There are some applications and required documents (in enforcement rules on cosmetics)

- (Notification for some amendments) Changes should be reported to the Regional Office of Food and Drug Safety.

\* Some modifications in brand names or address of manufacturing business, names of representatives or compound regulators, etc.

## **Management of Customized Cosmetics Businesses**

- Customized Cosmetics sellers should employ at least one customized cosmetics technical manager in their shop.

- Only qualified customized cosmetics technical managers have the right to compound and divide cosmetics.

## **Facility Standards for Customized Cosmetics Shops (Recommendations)**

- There must be designated sites for selling and creating Customized

Cosmetics (and also for storing materials and substances).

- There must be appropriate facilities for ventilation.
- There must be facilities for cleansing the technical managers' hands and compounding equipment.
- There must be facilities for preventing contaminants or spreading microorganisms from the process of compounding and dividing Customized Cosmetics.

### **Management of Sanitation for Technical Managers**

- Technical managers must wear disposable gloves before mixing or dividing Customized Cosmetics. Otherwise, they must disinfect or cleanse their hands.
- Technical managers must wear a face mask and a disinfected overgarment when compounding or dividing.
- Technical managers are prohibited from handling (compounding and dividing) Customized Cosmetics if they have skin diseases or wounds.

### **Management of Sanitation for Working Facilities and Equipment**

- Working facilities and equipment must be inspected on a regular basis to manage their sanitation.
- Working facilities and equipment used for mixing and dividing must be cleansed before and after their use.
- Detergents can be used provided that they do not cause any unexpected interactions, and do not remain on the surfaces.
- Cleansed facilities or equipment must be fully air-dried before their next use to prevent potential contamination.

### **Management Procedures for Warehousing and Storing Ingredients**

- When ingredients are warehoused, quality control and expiration dates must be checked. In addition, qualification evaluation needs to be verified. (Recommended)
- Substances must be kept in storages where their quality cannot be influenced by other factors.
- Ingredients must be inspected to prevent the use of expired materials in compounding Customized Cosmetics.

### **Management of the Sale of Customized Cosmetics**

- Sales records must be written up and stored (including manufacturing lot number (batch code), date sold, amount sold, shelf life (best before date or period after opening))
- Consumers must fully understand the explanations of the precautions for materials and substances used for Customized Cosmetics.

### **Post-Management of Customized Cosmetics**

- When safety issues (including adverse effects) are detected, Customized Cosmetics sellers must immediately notify the MFDS.

### **Customized Cosmetics Technical Manager**

- (Definition) A person who is responsible for compounding or dividing Customized Cosmetics at shops.
- (Qualification) Anyone seeking to become a Customized Cosmetics technical manager must pass a qualification exam administered by the MFDS and acquire the relative certification.
- (Requirement) Supplementary training must be taken each year.